UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION THIS DOCUMENT RELATES TO: *City of Alexandria, Virginia, v. Eli Lilly and Company, et al.*, Case No. 2:23-cv-22769	Case No. 2:23-md-03080 (BRM)(RLS) MDL No. 3080 JUDGE BRIAN R. MARTINOTTI JUDGE RUKHSANAH L. SINGH AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

FIGURES

Plaintiff, the City of Alexandria, Virginia, brings this action against the above-named Defendants and alleges as follows:

I. INTRODUCTION

A. Background

1. The cost of diabetes medications has skyrocketed over the past 20 years. Over that time, while the average cost of consumer goods and services has risen 1.75-fold, the cost of some diabetes medications has risen more than 10-fold. These price increases are not due to the rising cost of goods, production costs, investment in research and development, or competitive market forces. These price increases have been engineered by Defendants to exponentially increase their profits at the expense of payors, like Plaintiff, and its plan members. It is a multi-billion-dollar industry.

2. Diabetes is widespread. According to the American Diabetes Association, the total estimated cost of diabetes in the United States in 2017 was $327 billion. One in four healthcare dollars is spent caring for people with diabetes.

3. In Virginia alone, diabetes costs about $6.1 billion per year in direct medical expenses.[1]

[1] *See* American Diabetes Association, *The Burden of Diabetes in Virginia* (Apr. 2022), https://diabetes.org/sites/default/files/2023-09/ADV_2023_State_Fact_sheets_all_rev_Virginia.pdf (last visited Sept. 18, 2023).

4. Over 701,000 people in Virginia—about 10.4% of the adult population—have diabetes.[2] In the City of Alexandria, as of 2015, about 4.4% of adults were living with diabetes.[3]

5. Defendants Eli Lilly, Novo Nordisk, and Sanofi (collectively, the "Manufacturer Defendants" or "Manufacturers") manufacture nearly all insulins and other diabetes medications available in the United States. In 2020—as in years past—the three Manufacturer Defendants controlled 92% (by volume) and 96% (by revenue) of the global market for diabetes drugs.

6. Defendants CVS Caremark, Express Scripts, and OptumRx (collectively, the "PBM Defendants") are pharmacy benefit managers that work in concert with the Manufacturers to dictate the availability and price of the at-issue drugs for most of the U.S. market.[4] The PBM Defendants are, at once, (a) the three largest PBMs in the United States (controlling more than 80% of the PBM market); (b) the largest pharmacies in the United States (comprising three of the top five dispensing pharmacies in the United States); and (c) housed within the same corporate

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[2] *Id.*

[3] Alexandria Health Department, Health Profile I: Health Behaviors, Morbidity, and Mortality at 29 (2015), https://media.alexandriava.gov/docs-archives/health/webboxes/health-profile-i.pdf (last visited Oct. 9, 2023).

[4] For purposes of this Complaint, the "at-issue drugs" or "at-issue medications" include: Apidra, Basaglar, Humalog, Humulin N, Humulin R, Humulin R 500, Humulin 70/30, Lantus, Levemir, Novolin N, Novolin R, Novolin 70/30, Novolog, Ozempic, Soliqua, Toujeo, Tresiba, Trulicity, and Victoza.

enterprises as three of the largest insurance companies in the United States—Aetna (CVS Health), Cigna (Express Scripts), and UnitedHealthcare (OptumRx).

7. These conglomerate Defendants sit at 6th (CVS Health), 5th (UnitedHealth Group), and 15th (Cigna) on the Fortune 500 list.

Figure 1: Manufacturers, PBMs & PBM-Affiliated Insurers

PBMs	PBM-Affiliated Insurer
CVS	Aetna
Express Scripts	Cigna
Optum	UnitedHealthcare

8. For transactions in which the PBM Defendants control the insurer, the PBM, and the pharmacy (e.g., Aetna–Caremark–CVS Pharmacy)—these middlemen capture as much as half of the money spent on each insulin prescription (up from 25% in 2014), even though they contribute nothing to the innovation, development, manufacture, or production of the drugs.

9. The PBMs establish national formulary offerings (i.e., approved drug lists) that, among other things, set the baseline for which diabetes medications are covered and which are not covered by nearly every payor in the United States, including in Virginia and, more specifically, the City of Alexandria.

10. The Manufacturers and PBMs understand that the PBMs' national formularies drive drug utilization. The more accessible a drug is on the PBMs' national formularies, the more that drug will be purchased throughout the United

States. Conversely, the exclusion of a drug from one or more of the PBMs' formularies can render the drug virtually inaccessible for millions of covered persons.

11. Given the PBMs' market power and the crucial role their standard formularies play in the pharmaceutical pricing chain, both Defendant groups understand that the PBM Defendants wield enormous influence over drug prices and purchasing behavior.

12. The unfair and deceptive conspiracy at the root of this Complaint—the "Insulin Pricing Scheme"—was borne from this mutual understanding.

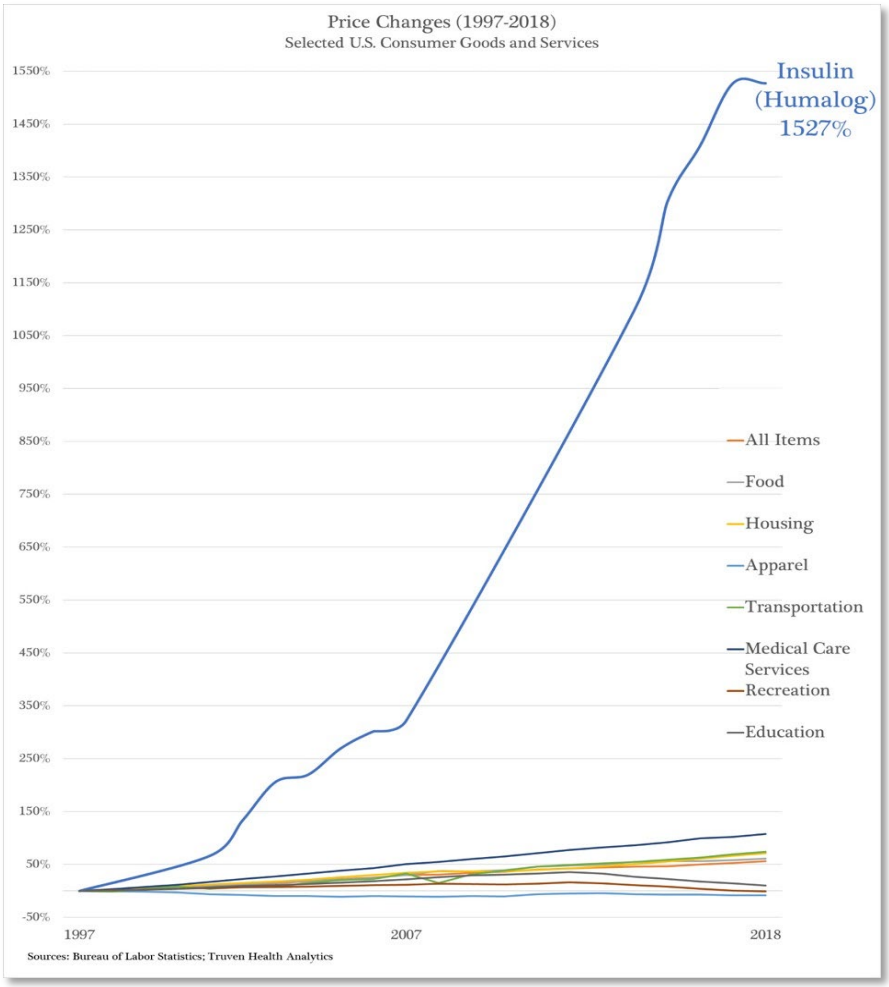
13. The Manufacturers set the initial list price—i.e., wholesale acquisition cost (WAC)—for their respective insulin medications. Over the last 20 years, list prices have sharply increased in lockstep, even though the cost to produce these drugs has decreased during that period.

14. Insulins, which today cost Manufacturers as little as $2 per vial to produce, and which originally were priced at $20 per vial in the 1990s, now range in price from $300 to $700.

15. The Manufacturer Defendants have in tandem increased the prices of their insulins up to 1000%, taking the same increase down to the decimal point within a few days of one another and, according to a U.S. Senate Finance Committee

investigation, "sometimes mirroring" one another in "days or even hours."5 Figure 2 reflects the rate at which Defendant Eli Lilly raised the list price of its analog insulin, Humalog, compared to the rate of inflation for other consumer goods and services during the period from 1997-2018.

Figure 2: Price Increase of Insulin (Humalog) vs. Selected Consumer Goods, 1997-2018



[5] Charles E. Grassley & Ron Wyden, *Staff Report on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, *Sen. Fin. Comm.*, at 6, 54, 55 (Jan. 2021), https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf(hereinafter "Senate Insulin Report").

16. Today's exorbitant prices are contrary to the intent of insulin's inventors, who sold their original patent rights to the University of Toronto for $1 each, reasoning that "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one secure a profitable monopoly." One of the inventors, Sir Frederick Banting, MD, stated that "[i]nsulin does not belong to me, it belongs to the world." But today, in stark contrast to its inventor's noble aims, insulin is the poster child for skyrocketing pharmaceutical prices.

17. Little about these medications has changed over the past 100 years; today's $350 insulin is essentially the same product the Manufacturers sold for $20 in the 1990s.

B. How the Insulin Pricing Scheme Works

18. In the simplest terms, there are three important participants in the insulin medication chain.

a. *Health Insurance Plans.* Health insurance plans, often funded by employers, provide cost coverage and reimbursements for medical treatment and care of individuals. These plans often include pharmacy benefits, meaning that the health plan pays a substantial share of the purchase price of its participants' prescription drugs, including the at-issue diabetes medications. Operators of these plans may be referred to as payors or plan sponsors (or PBM "clients"). The three main types of

payors are government/public payors, commercial payors, and private payors.

b. *PBMs.* Payors routinely engage pharmacy benefit managers (PBMs) to manage their prescription benefits, which includes negotiating prices with drug manufacturers and (ostensibly) helping payors manage drug spending. Each PBM maintains a formulary—a list of covered medications. A PBM's power to include or exclude a drug from its formulary theoretically should incentivize manufacturers to lower their list prices. PBMs also contract with pharmacies to dispense medications purchased by the plan's participants. PBMs are compensated by retaining a portion of what—again in theory—should be shared savings on the cost of medications.

c. *Manufacturers.* Manufacturers produce the at-issue insulin medications.[6] Each sets a list price for its products. The term "list price" often is used

[6] There are three types of insulin medications. First are *biologics,* which are manufactured insulins derived from living organisms. Second are *biosimilars*, which are "highly similar" copies of biologics. They are similar in concept to "generic" drugs; but in seeking approval, biosimilars use biologics (rather than drugs) as comparators. Third, the confusingly-named *authorized generics* are not true generics—they are an approved brand-name drug marketed without the brand name on the label. FDA approved the original insulins as drug products rather than biologics, so although there was a regulatory pathway to introduce biosimilars generally (copies of biologics), companies could not introduce insulin biosimilars because their comparators were "drugs" rather than "biologics." In 2020, FDA

interchangeably with the Wholesale Acquisition Cost (WAC) (defined by federal law as the undiscounted list price for a drug or biologic to wholesalers or direct purchasers). The manufacturers self-report list prices to publishing compendiums such as First DataBank, Medi-Span, or Redbook, who then publish those prices.[7]

19. Given the PBMs' purchasing power and their control over formularies that govern the availability of drugs, their involvement should theoretically drive down list prices because drug manufacturers normally compete for inclusion on the standard national formularies. For insulin, however, to gain access to the PBMs' formularies, the Manufacturers artificially *inflate* their list prices and then pay a significant, yet undisclosed, portion of that inflated price back to the PBMs (collectively, the "Manufacturer Payments").[8] The Manufacturer Payments bear a variety of dubious labels, including rebates, discounts, credits, inflation/price

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moved insulin to the biologic regulatory pathway, thereby opening the door to approval of biosimilars through an abbreviated approval process.

[7] The related term "Average Wholesale Price" (AWP) is the published price for a drug sold by wholesalers to retailers.

[8] In this Complaint, "Manufacturer Payments" is defined to include all payments or financial benefits of any kind conferred by the Manufacturer Defendants to the PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on a PBM Defendant's behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments includes rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, and any other form of consideration exchanged.

protection fees, and administrative fees. By whatever name, the inflated list prices and resulting Manufacturer Payments are a quid pro quo for inclusion and favorable placement on the PBMs' formularies.[9]

20. Contracts between PBMs and payors like Plaintiff tie the definition of "rebates" to patient drug utilization. But the contracts between PBMs and Manufacturers define "rebates" and other Manufacturer Payments differently, e.g., by calling rebates for formulary placement "administrative fees." Defendants thus profit from the "rebates" and other Manufacturer Payments, which are shielded from payors' contractual audit rights, thereby precluding payors from verifying the components or accuracy of the "rebates" that payors receive.

21. The PBM Defendants' staggering revenues vastly exceed the fair market value of the services they provide—both generally and with respect to the at-issue drugs.

22. The Manufacturers' initial list prices (WAC) for the at-issue drugs are not the result of free-market competition for payors' business. To the contrary, their list prices are so exorbitant in comparison to the net prices they ultimately realize that the Manufacturers know their initial list prices constitute a false price. These list

[9] Favorable or preferred placement may, for example, involve placing a branded product in a lower cost-sharing tier or relaxing utilization controls (such as prior authorization requirements or quantity limits). Favorable placement of a relatively more expensive drug encourages use of that drug and leads to higher out-of-pocket costs for payors and co-payors.

prices reflect neither the Manufacturers' actual costs to produce the at-issue drugs nor the fair market value of those drugs. Rather, they are artificially inflated solely to facilitate the Insulin Pricing Scheme.[10]

23. The PBM Defendants grant formulary status based on (a) the highest inflated price—which the PBMs know to be false—and (b) which diabetes medications generate the largest profits for themselves.

24. The Insulin Pricing Scheme thus creates a "best of both worlds" scenario for Defendants. The Manufacturers buy formulary access and thereby increase their sales and revenues, while the PBM Defendants receive significant, secret Manufacturer Payments based on the Manufacturers' inflated list prices.

25. The PBM Defendants profit off the Insulin Pricing Scheme in many ways, including: (a) retaining a significant, yet secret, share of the Manufacturer Payments, either directly or through rebate aggregators, (b) using the price produced by the Insulin Pricing Scheme to generate unwarranted profits from pharmacies, and (c) relying on those same artificial list prices to drive up the PBMs' margins and pharmacy-related fees, including those relating to their mail-order pharmacies. In

[10] "Net price" refers to the price the manufacturer ultimately realizes, i.e., the list price less rebates, and other discounts (net sales divided by volume). At times, Defendants' representatives use "net price" to refer to the amount payors or plan members pay for medications. In this Complaint, "net price" refers to the former—the amount that the Manufacturers realize for the at-issue drugs, which is roughly the List Price less Manufacturer Payments.

addition, because the PBM Defendants claim that they can extract higher rebates due to their market power, ever-rising list prices increase demand for PBMs' purported negotiation services.

26. As detailed below, although the PBM Defendants represent both publicly and directly to their client payors that they use their market power to drive down prices for diabetes medications, these representations are false and deceptive. Instead, the PBMs intentionally incentivize the Manufacturers to inflate their list prices. The PBMs' "negotiations" intentionally drive up the price of the at-issue drugs and are directly responsible for the skyrocketing prices of diabetes medications, conferring unearned benefits upon the PBMs and Manufacturers alike.

27. Because the purchase price of every at-issue diabetes medication flows from the false list prices generated by Defendants' unfair and deceptive scheme, every payor in the United States that purchases these life-sustaining drugs, including Plaintiff, has been directly harmed by the Insulin Pricing Scheme.

28. Even if temporary reductions in Plaintiff's costs for the at-issue drugs occurred from time to time, those costs still remained higher than costs that would have resulted from a transparent exchange in a free and open market.

29. As a payor for and purchaser of the at-issue drugs, Plaintiff the City of Alexandria has been overcharged substantial amounts of money during the relevant period as a direct result of the Insulin Pricing Scheme.

30. A substantial proportion of these overcharges is attributable to the artificially inflated prices of the at-issue drugs, which arose not from transparent or competitive market forces, but from undisclosed, opaque, and unlawful dealings between the Manufacturer Defendants and the PBM Defendants.

31. This action alleges that Defendants violated the Racketeer Influenced and Corrupt Organizations Act and Virginia law by engaging in the Insulin Pricing Scheme. The Insulin Pricing Scheme directly and foreseeably caused, and continues to cause, harm to Plaintiff.

32. This action seeks injunctive relief, restitution, disgorgement, damages, civil penalties, attorneys' fees and costs, and all other available relief to address and abate the harm caused by the Insulin Pricing Scheme.

33. The "relevant period" alleged in this action is from 2003 through the present.

II. PARTIES

A. Plaintiff

34. Plaintiff, the City of Alexandria, Virginia, is a unit of local government under the Virginia Constitution.

35. Plaintiff, as a government entity, provides vital services including public safety, emergency management, and health services to over 158,000 residents.

36. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to provide necessary services to the community.

37. The Insulin Pricing Scheme has had such an effect.

38. Additionally, as a government employer, Plaintiff provides health benefits to its employees, retirees, and their dependents ("Plan Participants"). One of the benefits Plaintiff offers its Plan Participants is paying a substantial share of the purchase price of their pharmaceutical drugs, including the at-issue diabetes medications.

39. Plaintiff seeks relief for the harm suffered by Defendants' misrepresentations and omissions regarding their illegal Insulin Pricing Scheme.

B. The Manufacturer Defendants

1. Eli Lilly

40. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

41. Eli Lilly is and has since 1968 been registered to do business in the Commonwealth of Virginia. Eli Lilly may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

42. Eli Lilly holds two pharmacy licenses in Virginia.

43. In Virginia and nationally, Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications, including: Humulin N (first U.S. approval in 1982), Humulin R (first U.S. approval in 1982), Humalog (first U.S. approval in 1996), Trulicity (first U.S. approval in 2014), and Basaglar (first U.S. approval in 2015).

44. Eli Lilly's domestic revenues from 2019 to 2021 were $11.9 billion from Trulicity, $4.48 billion from Humalog, $2.58 billion from Humulin and $2.31 billion from Basaglar.[11]

45. Eli Lilly's global revenues in 2018 were $3.2 billion from Trulicity, $2.99 billion from Humalog, $1.33 billion from Humulin and $801 million from Basaglar.[12]

46. Eli Lilly transacts business in Virginia, including in the City of Alexandria, targeting these markets for its products, including the at-issue diabetes medications.

47. Eli Lilly employs sales representatives throughout Virginia to promote and sell Humulin N, Humulin R, Humalog, Trulicity, and Basaglar and it utilizes wholesalers (McKesson, Amerisource Bergen, and Cardinal Health) to distribute the

[11] Eli Lilly Annual Report (Form 10-K) (FYE Dec. 31, 2021).
[12] Eli Lilly Annual Report (Form 10-K) (FYE Dec. 31, 2018).

at-issue products to pharmacies and healthcare professionals within Virginia, including in the City of Alexandria.

48. Eli Lilly also directs advertising and informational materials to Virginia physicians and potential users of Eli Lilly's products.

49. At all relevant times, in furtherance of the Insulin Pricing Scheme, Eli Lilly published its prices for the at-issue diabetes medications throughout Virginia with the express knowledge that payment and reimbursement by Plaintiff would be based on those false list prices.

50. During the relevant period, Plaintiff purchased Eli Lilly's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

51. All of the Eli Lilly diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Virginia based on the specific false and inflated prices Eli Lilly caused to be published in Virginia in furtherance of the Insulin Pricing Scheme.

2. Sanofi

52. Defendant Sanofi-Aventis U.S. LLC ("Sanofi") is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

53. Sanofi may be served through its registered agent: Corporation Service Company, 100 Shockoe Slip Fl 2, Richmond, Virginia 23219.

54. Sanofi holds three pharmacy licenses in Virginia.

55. Sanofi manufactures, promotes, and distributes pharmaceutical drugs both in Virginia and nationally, including several at-issue diabetes medications, including: Lantus (first U.S. approval in 2000), Apidra (first U.S. approval in April 2004), Toujeo (first U.S. marketing authorization in February 2015), and Soliqua (first U.S. approval in November 2016).

56. Sanofi considers Lantus one of its "flagship products" and "one of Sanofi's leading products in 2021 with net sales of €2,494 million" ($2.95 billion), as well as net sales of €2,661million ($3.04 billion) in 2020, representing 7.4% of the company's net sales for 2020.[13]

57. Sanofi's U.S. net sales in 2019 were $1.29 billion from Lantus, $323.7 million from Toujeo, and $51.5 million from Apidra.[14]

58. Sanofi transacts business in Virginia, including in the City of Alexandria, targeting these markets for its products, including the at-issue diabetes medications.

[13] Sanofi Annual Report (Form 20-F) (FYE Dec. 31, 2021); Sanofi Annual Report (Form 20-F) (FYE Dec. 31, 2020).

[14] Sanofi Annual Report (Form 20-F) (FYE Dec. 31, 2019).

59. Sanofi employs sales representatives throughout Virginia and in this District to promote and sell Lantus, Toujeo, Apidra, and Soliqua, and it utilizes wholesalers to distribute the at-issue products to pharmacies and healthcare professionals within Virginia.

60. Sanofi also directs advertising and informational materials to Virginia physicians and potential users of Sanofi's products for the specific purpose of selling the at-issue drugs in Virginia and profiting from the Insulin Pricing Scheme.

61. At all relevant times, in furtherance of the Insulin Pricing Scheme, Sanofi published prices of its at-issue diabetes medications throughout Virginia for the purpose of payment and reimbursement by payors, including Plaintiff.

62. During the relevant period, Plaintiff purchased Sanofi's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

63. All of the Sanofi diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Virginia based on the specific false and inflated prices Sanofi caused to be published in Virginia in furtherance of the Insulin Pricing Scheme.

3. Novo Nordisk

64. Defendant Novo Nordisk Inc. ("Novo Nordisk") is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

65. Novo Nordisk is and has since 2010 been registered to do business in the Commonwealth of Virginia. Novo Nordisk may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

66. Novo Nordisk manufactures, promotes, and distributes pharmaceutical drugs both in Virginia and nationally, including: Novolin R (first U.S. approval in 1991), Novolin N (first U.S. approval in 1991), Novolog (first U.S. approval in June 2002), Levemir (first U.S. approval in June 2005), Victoza (first U.S. approval in January 2010), Tresiba (first U.S. approval in 2015), and Ozempic (first U.S. approval in 2017).

67. Novo Nordisk's combined net sales of these drugs in the United States from 2018 to 2020 totaled approximately $18.1 billion ($6.11 billion for Victoza alone).[15]

[15] Novo Nordisk Annual Report (Form 20-F & Form 6-K) (FYE Dec. 31, 2020).

68. Novo Nordisk's global revenues for "total diabetes care" over that three-year period exceeded $41 billion.[16]

69. Novo Nordisk transacts business in Virginia and in the City of Alexandria, targeting these markets for its products, including the at-issue diabetes medications.

70. Novo Nordisk employs sales representatives throughout Virginia to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic, and it utilizes wholesalers to distribute the at-issue products to pharmacies and healthcare professionals within Virginia, including in the City of Alexandria.

71. Novo Nordisk also directs advertising and informational materials to Virginia physicians and potential users of Novo Nordisk's products.

72. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Novo Nordisk published its prices of its at-issue diabetes medications throughout Virginia for the purpose of payment and reimbursement by Plaintiff.

73. During the relevant period, Plaintiff purchased Novo Nordisk's at-issue diabetes medications at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

74. All of the Novo Nordisk diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Virginia based on the specific false

[16] *Id.*

and inflated prices Novo Nordisk caused to be published in Virginia in furtherance of the Insulin Pricing Scheme.

75. As set forth above, Eli Lilly, Sanofi, and Novo Nordisk are referred to collectively as the "Manufacturer Defendants" or the "Manufacturers."

C. PBM Defendants

1. CVS Caremark

76. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895.

77. CVS Health transacts business and has locations throughout the United States and Virginia.

78. CVS Health—through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers—is directly involved in creating and implementing the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs involved in the Insulin Pricing Scheme.

79. CVS Health's conduct had a direct effect in Virginia and damaged Plaintiff as a payor and purchaser.

80. On a regular basis, CVS Health executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

81. In each annual report for at least the last decade, CVS Health (or its predecessor) has repeatedly and explicitly stated that CVS Health itself:

a. designs pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members;

b. negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists, and these negotiated discounts enable CVS Health to offer reduced costs to clients; and

c. utilizes an independent panel of doctors, pharmacists, and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on its drug lists.[17]

82. CVS Health publicly represents that it lowers the cost of the at-issue drugs. For example, in 2016 CVS Health announced a new program to "reduce overall spending in diabetes" that is available in all states, including Virginia, stating that CVS Health:

[17] CVS Health Annual Report (Form 10-K) (FYE Dec. 31, 2009-2022).

> introduced a new program available to help the company's pharmacy benefit management (PBM) clients to improve the health outcomes of their members, *lower pharmacy costs [for diabetes medications]* through aggressive trend management and decrease medical costs . . . [and that] participating clients could save between $3,000 to $5,000 per year for each member who successfully improves control of their diabetes." (emphasis added)

83. A 2017 CVS Health report stated that "*CVS Health* pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year the lowest in five years. Despite manufacturer price increases of near 10 percent, *CVS Health* kept drug price growth at a minimal 0.2 percent."

84. In November 2018, CVS Health acquired Aetna for $69 billion and became the first combination of a major health insurer, PBM, and mail-order and retail pharmacy chain. As a result, CVS Health controls the health plan/insurer, the PBM, and the pharmacies utilized by approximately 40 million Aetna members in the United States and in Virginia. CVS Health controls the entire drug pricing chain for these 40 million Americans.

85. CVS Health is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Virginia—including CVS Pharmacy, Inc., which is registered to do business in the state—that dispensed and received payment for the at-issue diabetes medications throughout the relevant period. According to CVS Health's 2022 Form 10-K filed with the U.S. Securities and Exchange Commission, the company "maintains a national network

of approximately 66,000 retail pharmacies, consisting of approximately 40,000 chain pharmacies (which include CVS Pharmacy locations) and approximately 26,000 independent pharmacies, in the United States."[18]

86. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island corporation whose principal place of business is at the same location as CVS Health.

87. CVS Pharmacy—a wholly owned subsidiary of CVS Health—is and has since 1996 been registered to do business in the Commonwealth of Virginia. CVS Pharmacy may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

88. CVS Pharmacy is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Virginia, and it is directly involved in these pharmacies' policies for dispensing and payment related to the at-issue diabetes medications.

89. CVS Pharmacy is also the immediate and direct parent of Defendant Caremark Rx, LLC.

90. CVS Pharmacy holds four licenses, including two pharmacy licenses, in Virginia.

[18] CVS Health Annual Report (Form 10-K) (FYE Dec. 31, 2022).

91. During the relevant period, CVS Pharmacy provided retail pharmacy services in Virginia that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

92. Defendant Caremark Rx, LLC is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail-order subsidiaries that engaged in the activities in Virginia that gave rise to this action.

93. Caremark Rx, LLC is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health, and its principal place of business is at the same location as CVS Pharmacy and CVS Health.

94. During the relevant period, Caremark Rx, LLC provided PBM and mail-order pharmacy services in Virginia that gave rise to and implemented the Insulin Pricing Scheme and damaged payors in Virginia, including Plaintiff.

95. Defendant Caremark, LLC is a California limited liability company whose principal place of business is at the same location as CVS Health.

96. Caremark, LLC is a subsidiary of Caremark Rx, LLC, which is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health.

97. Caremark, LLC is and has since 2007 been registered to do business in Virginia. Caremark, LLC may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

98. Caremark, LLC (dba CVS/Specialty) holds one or more wholesaler licenses and holds at least three pharmacy licenses in Virginia.

99. During the relevant period, Caremark, LLC provided PBM and mail-order pharmacy services in Virginia that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

100. Defendant CaremarkPCS Health, LLC ("CaremarkPCS Health") is a Delaware limited liability company whose principal place of business is at the same location as CVS Health.

101. CaremarkPCS Health is a subsidiary of CaremarkPCS, LLC, which is a subsidiary of Caremark Rx, LLC, which is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health.

102. CaremarkPCS Health is and has since 2013 been registered to do business in Virginia. CaremarkPCS Health may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

103. CaremarkPCS Health, doing business as CVS Caremark, provides pharmacy benefit management services.

104. During the relevant period, CaremarkPCS Health provided PBM services in the Commonwealth of Virginia, which gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

105. Defendants CaremarkPCS Health and Caremark, LLC are agents and/or alter egos of Caremark Rx, LLC, CVS Pharmacy, and CVS Health.

106. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control CaremarkPCS Health and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction, Manufacturer Payments, and mail-order and retail pharmacy services to the ultimate detriment of Plaintiff. For example:

a. During the relevant period, these parent and subsidiaries have had common officers and directors, including:

- Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health, and Caremark, LLC, also served as Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and the Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;

- Melanie K. Luker, Assistant Secretary of Caremark Rx, LLC, CaremarkPCS Health, and Caremark, LLC, also served as Manager of Corporate Services at CVS Health;
- Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, also served as Senior Vice President, Treasurer and Chief Risk Officer at CVS Health;
- John M. Conroy was Vice President of Finance at CVS Health beginning in 2011 and also was President and Treasurer of Caremark, LLC and CaremarkPCS Health in 2019;
- Sheelagh Beaulieu served as Senior Director of Income Tax at CVS Health while also acting as the Assistant Treasurer at CaremarkPCS Health and Caremark, LLC.

b. CVS Health owns all the stock of CVS Pharmacy, which owns all the stock of Caremark Rx, LLC, which owns all the stock of Caremark LLC. CVS Health directly or indirectly owns CaremarkPCS Health in its entirety.

c. CVS Health, as a corporate unit, does not operate as separate entities. Rather, its public filings, documents and statements present its subsidiaries—including CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC, and CaremarkPCS Health—as divisions or departments of one

unified "diversified health services company" that "works together across our disciplines" to "create unmatched human connections to transform the health care experience." The day-to-day operations of this corporate unit reflect these public statements. These entities constitute a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.[19]

d. All executives of CaremarkPCS Health, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including its President and CEO.

e. As stated above, CVS Health's CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents and Chief Communication Officers are directly involved in the policies and business decisions by Caremark, LLC and CaremarkPCS Health that give rise to Plaintiff's claims.

107. Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC, and CaremarkPCS Health, including all predecessor and successor entities, are referred to collectively as "CVS Caremark."

[19] CVS Health Annual Report (Form 10-K) (FY 2009-2019); CVS Health, *Our Purpose,* https://cvshealth.com/about-cvs-health/our-purpose (last visited Sept. 9, 2022); CVS Health, *Quality of Care,* https://cvshealth.com/health-with-heart/improving-health-care/quality-of-care (last visited Sept. 9, 2022).

108. CVS Caremark is named as a Defendant in its capacities as a PBM and as a mail-order pharmacy.

109. In its capacity as a PBM, CVS Caremark coordinated with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these firms' diabetes medications on CVS Caremark's formularies.

110. CVS Caremark has the largest PBM market share based on total prescription claims managed. Its pharmacy services segment provides, among other things, plan design offerings and administration, formulary management, retail pharmacy network management services, mail-order pharmacy, specialty pharmacy and infusion services, clinical services, and medical spend management. In 2021, CVS Caremark's pharmacy services segment "surpassed expectations" and had a "record selling season of nearly $9 billion in net new business wins for 2022." In all, it generated just over $153 billion in total revenues (on top of total 2019-2020 segment revenues exceeding $283 billion).[20]

111. At all relevant times, CVS Caremark offered pharmacy benefit services nationwide and to Virginia payors, and derived substantial revenue therefrom, and, in doing so, (a) made misrepresentations while concealing the Insulin Pricing Scheme, and (b) utilized the false prices generated by the Insulin Pricing Scheme.

[20] CVS Health Annual Report (Form 10-K) (FYE Dec. 31, 2021).

112. At all relevant times, CVS Caremark offered PBM services nationwide and maintained standard formularies that were used nationwide, including in Virginia. Those formularies included diabetes medications, including those at issue in this action, and CVS Caremark participated in pricing the at-issue drugs based off the list prices it knew to be false.

113. CVS Caremark purchased drugs directly from manufacturers for dispensing through its pharmacy network.

114. Further, in its capacity as a retail pharmacy, CVS Caremark knowingly profited from the false list prices produced by the Insulin Pricing Scheme by pocketing the spread between the acquisition cost for the at-issue drugs (an amount well below the list price generated by the Insulin Pricing Scheme) and the amounts it received from payors (which amounts were based on the false list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

115. During the relevant period, CVS Caremark provided mail-order and retail pharmacy services nationwide and within the Commonwealth of Virginia and employed prices based on the false list prices generated by the Insulin Pricing Scheme.

116. At all relevant times, CVS Caremark dispensed the at-issue medications nationwide within the Commonwealth of Virginia through its mail-order and retail pharmacies and it derived substantial revenue from these activities in Virginia.

117. At all relevant times, CVS Caremark had express agreements with Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to CVS Caremark, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail-order pharmacies.

2. Express Scripts

118. Defendant Evernorth Health, Inc. ("Evernorth"), formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business at One Express Way, St. Louis, Missouri 63121.[21]

119. Evernorth, through its executives and employees, including its CEO and Vice Presidents, is directly involved in shaping the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs, related to the Insulin Pricing Scheme.

120. Evernorth's conduct had a direct effect in Virginia and upon Plaintiff.

121. On a regular basis, Evernorth executives and employees communicate with and direct Evernorth's subsidiaries related to the at-issue PBM services and formulary activities.

[21] Until 2021, Evernorth Health, Inc. operated under the name Express Scripts Holding Company. In this Complaint "Evernorth" refers to Evernorth Health, Inc. and Express Scripts Holding Company.

122. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Virginia, who engaged in the activities that gave rise to this action.[22]

123. In 2018, Evernorth merged with Cigna in a $67 billion deal to consolidate their businesses as a major health insurer, PBM, and mail-order pharmacy. As a result, the Evernorth corporate enterprise controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 15 million Cigna members in the United States, including in Virginia. Evernorth controls the entire drug pricing chain for these 15 million Americans.

124. Evernorth's annual reports over the past several years have repeatedly and explicitly:

a. Acknowledged that it is directly involved in the company's PBM services, stating "[Evernorth is] the largest stand-alone PBM company in the United States."

b. Stated that Evernorth controls costs, including for example, that it: "provid[es] products and solutions that focus on improving patient outcomes and assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty

[22] Express Scripts Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2018).

services that result in cost savings for plan sponsors and better care for members."[23]

125. Even after the merger with Cigna, Evernorth "operates various group purchasing organizations that negotiate pricing for the purchase of pharmaceuticals and formulary rebates with pharmaceutical manufacturers on behalf of their participants" and operates the company's Pharmacy Rebate Program while its subsidiary Express Scripts provides "formulary management services" that ostensibly "assist customers and physicians in choosing clinically-appropriate, cost-effective drugs and prioritize access, safety and affordability." In 2021, Evernorth reported adjusted revenues of $131.9 billion (representing 75.8% of Cigna Corporation's revenues), up from $116.1 billion in 2020.[24]

126. Defendant Express Scripts, Inc. is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts, Inc.'s principal place of business is at the same location as Evernorth.

127. Express Scripts, Inc. is and has since 2011 been registered to do business in Virginia and may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

128. Express Scripts, Inc. holds three pharmacy licenses in Virginia.

[23] Express Scripts Annual Reports (FY 2009-2019); Cigna Annual Report (Form 10-K) FYE 2020 & 2021).

[24] Cigna Annual Report (Form 10-K) (FYE Dec. 31, 2021).

129. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Virginia that engaged in the conduct that gave rise to this action.[25]

130. During the relevant period, Express Scripts Inc. was directly involved in PBM and mail-order pharmacy services that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

131. Defendant Express Scripts Administrators, LLC, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Its principal place of business is at 100 Parsons Pond Drive, Franklin Lakes, New Jersey 07417—the same location as Evernorth.

132. Express Scripts Administrators, LLC is, and has been since 2022, registered to do business in Virginia.

133. During the relevant period, Express Scripts Administrators, LLC provided the PBM services in Virginia that gave rise to and implemented the Insulin Pricing Scheme that damaged payors, including Plaintiff.

134. Defendant Medco Health Solutions, Inc. ("Medco") is a Delaware Corporation whose principal place of business is at the same location as Evernorth.

135. Medco was registered to do business in Virginia beginning in 2002.

[25] Express Scripts Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2018).

136. In 2012, Express Scripts acquired Medco for $29 billion.

137. Until its acquisition by Express Scripts, Medco's principal place of business was in Franklin Lakes, New Jersey.

138. Before the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Virginia.

139. Before the merger, Medco provided the at-issue PBM and mail-order services in Virginia, which gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

140. Following the merger, all of Medco's PBM and mail-order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's payor customers becoming Express Scripts' customers—including Plaintiff. The combined company covered over 155 million lives at the time of the merger.

141. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, David Snow, then-CEO of Medco, publicly represented that "the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined

entity will achieve even greater purchasing volume discounts [i.e., Manufacturer Payments] from drug manufacturers and other suppliers."[26]

142. At the same time, the then-CEO of Express Scripts, George Paz, provided written testimony to the Senate Judiciary Committee's Subcommittee on Antitrust, Competition Policy and Consumer Rights, stating: "A combined Express Scripts and Medco will be well-positioned to protect American families from the rising cost of prescription medicines." First on Mr. Paz's list of "benefits of this merger" was "[g]enerating greater cost savings for patients and plan sponsors."[27]

143. Defendant ESI Mail Pharmacy Service, Inc. is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. ESI Mail Pharmacy Service, Inc.'s principal place of business is at the same location as Evernorth.

144. During the relevant period, ESI Mail Pharmacy Services provided the mail-order pharmacy services in Virginia discussed in this Complaint, which gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

[26] Transcript available at https://www.judiciary.senate.gov/imo/media/doc/11-12-6SnowTestimony.pdf (last visited Sept. 14, 2023).

[27] Transcript available at https://www.judiciary.senate.gov/imo/media/doc/11-12-6PazTestimony.pdf (last visited Jan. 13, 2023).

145. Defendant Express Scripts Pharmacy, Inc. is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Evernorth.

146. Express Scripts Pharmacy, Inc. is and has been since at least 2021 registered to do business in Virginia and may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

147. Express Scripts Pharmacy, Inc. holds two pharmacy licenses in Virginia.

148. During the relevant period, Express Scripts Pharmacy, Inc. provided the mail-order pharmacy services in Virginia that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.

149. As a result of numerous interlocking directorships and shared executives, Evernorth (f/k/a Express Scripts Holding Company, Inc.) and Express Scripts, Inc. control Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc.'s operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. During the relevant period, these parent and subsidiaries have had common officers and directors:

- Officers and/or directors shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Managing Counsel; Dave Anderson, VP of Strategy; Matt Perlberg, President of Pharmacy Businesses; Bill Spehr, SVP of Sales; and Scott Lambert, Treasury Manager Director;
- Executives shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Senior Counsel;
- Officers and/or directors shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Priscilla Duncan, Associate Senior Counsel; and Joanne Hart, Treasury Director; and
- Officers and/or directors shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Jill Stadelman, Managing Counsel; Scott Lambert, Treasury Manager Director; and Joanne Hart, Treasury Director.

b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.[28]

c. The Evernorth corporate entity does not operate as separate entities. Evernorth's public filings, documents, and statements present its subsidiaries, including Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc. as divisions or departments of a single company that "unites businesses that have as many as 30+ years of experience . . . [to] tak[e] health services further with integrated data and analytics that help us deliver better care to more people." The day-to-day operations of this corporate organization reflect these public statements. All of these entities constitute a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint.[29]

d. All of the executives of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc. ultimately report to the executives, including the CEO, of Evernorth.

[28] Express Scripts Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2018).
[29] Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017).

e. As stated above, Evernorth's CEO and other executives and officers are directly involved in the policies and business decisions of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc. that gave rise to Plaintiff's claims in this Complaint.

150. Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc., including all predecessor and successor entities, are referred to collectively as "Express Scripts."

151. Express Scripts is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

152. In its capacity as a PBM, Express Scripts coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on Express Scripts' formularies.

153. Before merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States.[30] During the relevant period of this Complaint, Express Scripts controlled 30% of the PBM market in the United States. Express Scripts has only grown larger since the Cigna merger.

[30] *Id*.

154. In 2017, annual revenue for Express Scripts was over $100 billion.[31]

155. As of December 31, 2017, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.[32]

156. Express Scripts transacts business throughout the United States and Virginia.

157. At all relevant times, Express Scripts derived substantial revenue from providing retail and mail-order pharmacy benefits in Virginia using prices based on the false list prices for the at-issue drugs.

158. At all relevant times, and contrary to its express representations, Express Scripts knowingly insisted that its payor clients, including Plaintiff, use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

159. At all relevant times, Express Scripts concealed its critical role in the generation of those false list prices.

160. At all relevant times, Express Scripts maintained standard formularies that are used nationwide, including in the Commonwealth of Virginia. During the

[31] *Id.*

[32] *Id.*

relevant period, those formularies included drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications.

161. During part of the relevant period, Express Scripts provided PBM services to Plaintiff and, in doing so, Express Scripts set the price that Plaintiff paid for the at-issue drugs at prices based on the false list prices generated by the Insulin Pricing Scheme and Plaintiff paid Express Scripts for the at-issue drugs.

162. In its capacity as a mail-order pharmacy, Express Scripts received payments from Virginia payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

163. At all relevant times, Express Scripts offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Virginia. Those formularies included diabetes medications, including all identified in this Complaint.

164. Express Scripts purchases drugs directly from manufacturers for dispensing through its pharmacy network.

165. During the relevant period, Express Scripts dispensed the at-issue medications nationwide and directly to Plaintiff and/or its Plan Participants through its mail-order pharmacies and derived substantial revenue from these activities in Virginia.

166. During the relevant period, in addition to its critical role in the Insulin Pricing Scheme, which detrimentally affected all payors and purchasers of the at-issue drugs, Express Scripts also provided PBM services directly to Plaintiff.

167. During certain years when some of the largest at-issue price increases occurred, including in 2013 and 2014, Express Scripts worked directly with OptumRx to negotiate Manufacturer Payments on behalf of OptumRx and its clients in exchange for preferred formulary placement. For example, in a February 2014 email released by the U.S. Senate in conjunction with the January 2021 Senate Insulin Report, Eli Lilly describes a "Russian nested doll situation" in which Express Scripts was negotiating rebates on behalf of OptumRx related to the at-issue drugs for Cigna (who later would become part of Express Scripts).[33]

168. At all relevant times, Express Scripts had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to Express Scripts, as well as agreements related to the Manufacturers' at-issue drugs sold through Express Scripts' pharmacies.

[33] Letter from Joseph B. Kelley, Eli Lilly Vice President, Global Gov. Affairs, to Charles E. Grassley & Ron Wyden, S. Fin. Comm., https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf (last visited July 3, 2023).

3. OptumRx

169. Defendant UnitedHealth Group, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

170. UnitedHealth Group, Inc. is a diversified managed healthcare company. Its total revenues in 2022 exceeded $324 billion. In 2021, its revenues exceeded $287 billion. Since 2020, its revenues have increased by more than $30 billion from per year. The company currently sits fifth on the Fortune 500 list.[34]

171. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx.

172. Over one-third of UnitedHealth Group's total revenue is attributable to OptumRx, which operates a network of more than 67,000 pharmacies.

173. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that shape its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme. For example, UnitedHealth Group executives' structure, analyze, and direct the company's overarching policies, including as to PBM and mail-order services, as a means of maximizing profitability across the corporate organization.

[34] UnitedHealth Group, Inc. Annual Report (Form 10-K) (FYE Dec. 31, 2022).

174. UnitedHealth Group's Sustainability Report states that "OptumRx works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create tailored formularies – or drug lists – to ensure people get the right medications. [UnitedHealth Group] then negotiate[s] with pharmacies to lower costs at the point of sale . . . [UnitedHealth Group] also operate[s] [mail order pharmacies] . . . . [UnitedHealth Group] work[s] directly with drug wholesalers and distributors to ensure consistency of the brand and generic drug supply, and a reliance on that drug supply."

175. In addition to being a PBM and a mail-order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by more than 26 million UnitedHealthcare members in the United States, including in Virginia. UnitedHealth Group controls the entire drug pricing chain for these 26 million Americans.

176. UnitedHealth Group's conduct had a direct effect in Virginia and damaged Plaintiff.

177. UnitedHealth Group states in its annual reports that UnitedHealth Group "uses Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience." Its 2022

annual report states plainly that it is "involved in establishing the prices charged by retail pharmacies, determining which drugs will be included in formulary listings and selecting which retail pharmacies will be included in the network offered to plan sponsors' members …." As of year-end 2022 and 2021, UnitedHealth Group's "total pharmaceutical manufacturer rebates receivable included in other receivables in the Consolidated Balance Sheets amounted to $8.2 billion and 7.2, respectively," up even from $6.3 billion in 2020."[35]

178. Defendant Optum, Inc. is a Delaware corporation with its principal place of business in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Defendant OptumRx, Inc.[36]

179. Optum, Inc. has been since 2003 registered to do business in Virginia and may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

180. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction,

[35] UnitedHealth Group Annual Report (Form 10-K) (FYE Dec. 31, 2018); UnitedHealth Group Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2021); UnitedHealth Group Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2022).

[36] UnitedHealth Group Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2022).

including with respect to the at-issue drugs and related to the Insulin Pricing Scheme, which had a direct effect in Virginia and damaged Plaintiff.

181. For example, according to an Optum Inc. press release, Optum, Inc. is "UnitedHealth Group's information and technology-enabled health services business platform serving the broad healthcare marketplace, including care providers, plan sponsors, payers, life sciences companies and consumers." In this role, Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx" and the CEOs of all these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail-order activities.

182. Defendant OptumRx, Inc. is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614.

183. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Defendant Optum, Inc.

184. OptumRx, Inc. is, and has since 2008 been registered to do business in Virginia and may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

185. OptumRx, Inc. holds one pharmacy license in Virginia.

186. During the relevant period, OptumRx, Inc. provided the PBM and mail-order pharmacy services in Virginia that gave rise to and implemented the Insulin

Pricing Scheme, which damaged payors, including Plaintiff. OptumRx provided PBM services to Plaintiff during part of the relevant time period.

187. Defendant OptumInsight, Inc. ("OptumInsight") is a Delaware corporation with its principal place of business in Eden Prairie, Minnesota.

188. OptumInsight, Inc. is, and has been since 1997, registered to do business in Virginia and may be served through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

189. OptumInsight is an integral part of the Insulin Pricing Scheme and, during the relevant period, coordinated directly with the Manufacturer Defendants in furtherance of the conspiracy. OptumInsight analyzed data and other information from the Manufacturer Defendants to advise the other Defendants about the profitability of the Insulin Pricing Scheme to the benefit of all Defendants.

190. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings, LLC and Optum, Inc. are directly involved in the conduct of and control OptumInsight's and OptumRx's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. These parent and subsidiaries have common officers and directors, including:

- Andrew Witty is the CEO and on the Board of Directors for UnitedHealth Group and previously served as CEO of Optum, Inc.;
- Dirk McMahon is President and COO of UnitedHealth Group Inc. He served as President and COO of Optum from 2017 to 2019 and as CEO of OptumRx from 2011 to 2014;
- John Rex has been an Executive Vice President and CFO of UnitedHealth Group Inc. since 2016 and previously served in the same roles at Optum beginning in 2012;
- Dan Schumacher is Chief Strategy and Growth Officer at UnitedHealth Group Inc. and is CEO of Optum Insight, having previously served as president of Optum, Inc.;
- Terry Clark is a senior vice president and has served as chief marketing officer at UnitedHealth Group since 2014 while also serving chief marketing and customer officer for Optum;
- Tom Roos has served since 2015 as SVP and chief accounting officer for UnitedHealth Group Inc. and Optum, Inc.;
- Heather Cianfrocco joined UnitedHealth Group in 2008 and has held numerous leadership positions within the company while today she is CEO of OptumRx;

- Peter Gill has served as SVP and Treasurer for UnitedHealth Group, Inc. and also as Treasurer at OptumRx, Inc. and OptumRx PBM of Illinois, Inc.;
- John Santelli led Optum Technology, the leading technology division of Optum, Inc. serving the broad customer base of Optum and UnitedHealthcare and also served as UnitedHealth Group's chief information officer;
- Eric Murphy, now retired, was the Chief Growth and Commercial Officer for Optum, Inc. and also was CEO of OptumInsight beginning in 2017.

b. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc. and OptumInsight.

c. The UnitedHealth Group corporate unit does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions, departments or "segments" of a single company that is "a diversified family of businesses" that "leverages core competencies" to "help[] people live healthier lives and helping make the health system work better for everyone." The day-to-day operations of this corporate organization reflect these public statements. These entities

constitute a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint.[37]

d. All the executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.

e. As stated above, UnitedHealth Group's executives and officers are directly involved in the policies and business decisions of Optum, Inc., OptumRx, Inc., and OptumInsight that gave rise to Plaintiff's claims.

191. Defendants UnitedHealth Group, Inc., OptumRx, Inc., OptumInsight, and Optum, Inc., including all predecessor and successor entities, are collectively referred to as "OptumRx."

192. OptumRx is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

193. OptumRx is a pharmacy benefit manager and, as such, coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on OptumRx's drug formularies.

[37] *See, e.g.*, UnitedHealth Group, Quarterly Report (Form 10-Q) (FQE Mar. 31, 2017).

194. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities. It is one of UnitedHealth Group Inc.'s "four reportable segments" (along with UnitedHealthcare, Optum Health, and OptumInsight).

195. In 2022, OptumRx managed $124 billion in pharmaceutical spending.[38]

196. For the years 2018-2022, OptumRx managed $91 billion, $96 billion, $105 billion, $112 billion, and $124 billion in pharmaceutical spending, respectively.[39]

197. In 2019, Optum Rx's revenue (excluding UnitedHealthcare) totaled $74 billion. By 2022, it had risen to more than $99 billion.[40]

198. At all relevant times, OptumRx derived substantial revenue providing pharmacy benefits in Virginia.

199. At all relevant times, OptumRx offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Virginia. Those formularies included diabetes medications, including those at issue in this action. OptumRx purchased drugs directly from manufacturers for dispensing through its pharmacy network.

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[38] UnitedHealth Group Annual Report (Form 10-K) (FYE Dec. 31, 2022).

[39] *Id.*

[40] *Id.*

200. At all relevant times, and contrary to its express representations, OptumRx knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

201. At all relevant times, OptumRx concealed its critical role in the generation of those false list prices.

202. In its capacity as a mail-order pharmacy with a contracted network of retail pharmacies, OptumRx received payments from payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

203. At all relevant times, OptumRx dispensed the at-issue medications nationwide and in Virginia through its mail-order and retail pharmacies and derived substantial revenue from these activities in Virginia.

204. OptumRx purchases drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications, for dispensing through its mail-order pharmacies and network of retail pharmacies.

205. At all relevant times, OptumRx had express agreements with Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to OptumRx, as well as agreements related to the Manufacturers' at-issue drugs sold through OptumRx pharmacies.

206. As set forth above, CVS Caremark, OptumRx, and Express Scripts are referred to collectively as the "PBM Defendants."

III. JURISDICTION AND VENUE

A. Subject Matter Jurisdiction

207. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and pursuant to 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962. This Court has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

B. Personal Jurisdiction

208. This Court has personal jurisdiction over each Defendant. Each Defendant: (a) transacts business and/or is admitted to do business within Virginia; (2) maintains substantial contacts in Virginia, and (3) committed violations of Virginia statutes, federal statutes, and common law in whole or part within the Commonwealth of Virginia. This action arises out of and relates to each Defendant's contacts with this forum.

209. The Insulin Pricing Scheme has been directed at and has had the foreseeable and intended effect of causing injury to persons residing in, located in, or doing business in, Virginia. At-issue transactions occurred in the Commonwealth of Virginia and/or involved Virginia residents.

210. Each Defendant purposefully availed itself of the privilege of doing business within this state, including within this District; and each derived substantial financial gain from doing so. These continuous, systematic, and case-related business contacts—including the tortious acts described herein—are such that each Defendant should reasonably have anticipated being brought into this Court.

211. Each Defendant submitted itself to jurisdiction through, among other things, pervasive marketing; encouraging the use of its services; and its purposeful cultivation of profitable relationships in the Commonwealth of Virginia.

212. In short, each Defendant has systematically served a market in Virginia relating to the Insulin Pricing Scheme and has caused injury in Virginia such that there is a strong relationship among Defendants, this forum, and the litigation.

213. This Court has personal jurisdiction over all Defendants pursuant to Fed. R. Civ. P. 4(k)(1)(A) because they would be subject to the jurisdiction of a court of general jurisdiction in Virginia.

214. This Court also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single action for a single trial.

C. Venue

215. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in this District, and because a substantial part of the events or omissions giving rise to this action took place, or had their ultimate injurious impact, within this District. In particular, at all times during the relevant period, Defendants provided pharmacy benefit services, provided mail-order pharmacy services, employed sales representatives, promoted and sold diabetes medications, or published prices of the at issue drugs in this District.

216. Venue is also proper in this District pursuant to 18 U.S.C. § 1965, because all Defendants reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought before this Court.

IV. ADDITIONAL FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

1. The Diabetes Epidemic

217. Diabetes occurs when a person's blood glucose is too high. In people without diabetes, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to blood glucose. When insulin is lacking or when cells stop responding to insulin, however, blood sugar stays in the bloodstream. Over time,

this can cause serious health problems, including heart disease, blindness, and kidney disease.

218. There are two basic types of diabetes—Type 1 and Type 2. Roughly 90-95% of diabetics are Type 2, which develops when a person does not produce enough insulin or has become resistant to the insulin they produce. Although Type 2 patients can initially be treated with tablets, most patients eventually must switch to insulin injections.

219. Diabetes has been on the rise for decades. In 1958, only 1.6 million Americans had diabetes. By the turn of the century, however, that number had grown to over ten million. Fourteen years later, that number had tripled. Today, more than 37 million Americans—approximately 12% of the country—live with the disease.

220. The prevalence of diabetes in Virginia has increased as well. Over 733,300 Virginia adults now live with diabetes and another 2.1 million have prediabetes.

2. Insulin: A Century-Old Drug

221. Even though diabetes is the eighth leading cause of death in the United States, it is a treatable disease and has been for almost a century. Patients who follow a prescribed treatment plan consistently avoid severe health complications associated with the disease.

222. In 1922, Frederick Banting and Charles Best, while working at the University of Toronto, pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes. Banting and Best obtained a patent and then sold their patent rights to the University of Toronto for $1 (equivalent to $18 today), reasoning that "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[41] One of the inventors, Sir Frederick Banting, MD, stated that "[i]nsulin does not belong to me, it belongs to the world."[42]

223. After purchasing the patent, the University of Toronto contracted with Defendants Eli Lilly and Novo Nordisk to scale its production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

224. The earliest insulin was derived from animals and, until the 1980s, was the only treatment for diabetes. While effective, animal-derived insulin created the risk of allergic reaction. This risk was reduced in 1982 when synthetic insulin—known as human insulin because it mimics the insulin humans make—was developed by Eli Lilly. Compared to animal-derived insulin, human insulin is cheaper to mass-produce and causes fewer allergic reactions. Eli Lilly marketed this

[41] Michael Bliss, *The Discovery of Insulin* (2013).
[42] *Id*.

insulin as Humulin. The development of human insulin benefited heavily from government and non-profit funding through the National Institutes of Health and the American Cancer Society.

225. In the mid-1990s, Eli Lilly introduced the first analog insulin—a laboratory-grown and genetically altered insulin. These altered forms of human insulin are called "analogs" because they are analogous to the human body's natural pattern of insulin release and more quickly lower blood sugar. Eli Lilly released this analog in 1996 under the brand name Humalog at a cost of $21 per vial (equivalent to $40 in 2022).

226. Other rapid-acting analogs include Novo Nordisk's Novolog and Sanofi's Apidra, which have similar profiles. Rapid-acting insulins are used in combination with longer-acting insulins, such as Sanofi's Lantus and Novo Nordisk's Levemir.

227. The Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

228. In 2015, Sanofi introduced Toujeo, another long-acting insulin similar to Lantus. Toujeo, however, is highly concentrated, reducing injection volume as compared to Lantus.

229. In December 2015, Eli Lilly introduced Basaglar—a long-acting insulin that is biologically similar to Sanofi's Lantus.

230. Most insulin presently used in the United States is analog insulin and not human insulin. In 2000, 96% of insulin users used human insulin versus 19% using analog insulin. By 2010, the ratio had switched; only 15% of patients used human insulin while 92% used analog insulin. In 2017, for example, less than 10% of the units of insulin dispensed under Medicare Part D were human insulins.

231. Even though insulin was first extracted 100 years ago, and despite its profitability, Eli Lilly, Novo Nordisk and Sanofi still make nearly all of the insulin sold in the United States. This did not happen by chance.

232. Many of the at-issue medications are now off-patent. The Manufacturers maintain market domination through patent "evergreening." Drugs usually face generic competition when their 20-year patents expire. While original insulin formulas may technically be available for generic use, the Manufacturers "stack" patents around the original formulas, making new competition riskier and more costly. For example, Sanofi has filed more than 70 patents on Lantus—more than 95% were filed after the drug was approved by the FDA—potentially providing more than three additional decades of patent "protection" for the drug. The market therefore remains concentrated.

233. In 2021, the U.S. House of Representatives Committee on Oversight and Reform issued a report following its investigation into drug pricing ("Drug Pricing

Investigation").[43] It expressly included inquiry into the Manufacturer Defendants' insulin pricing strategies[44] and concluded: "Every company in the Committee's investigation engaged in one or more strategies to suppress competition from generics or biosimilars, and keep prices high."[45] It continued:

> Insulin manufacturers have also used secondary patents to extend their market monopolies. A 2020 study by the State of Colorado found, "Many insulin products have received additional patents, exclusivities, and extensions, adding decades of protection and monopoly prices." According to this study, secondary patents enabled Eli Lilly to add 17 years of protection for Humalog, Novo Nordisk to add 27 years of protection for NovoLog, and Sanofi to add 28 years of protection for Lantus.[46]

3. Current Insulin Landscape

234. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions about whether the overall efficacy of insulin has significantly improved over the last 20 years.

235. For example, while long-acting analogs may have certain advantages over human insulins, e.g., by providing greater flexibility around mealtime planning,

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[43] *Drug Pricing Investigation: Majority Staff Report*, Committee on Oversight and Reform U.S. House of Representatives December 2021, available at https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (last visited Aug. 11, 2023).

[44] *Id.*at PDF 4, n.5.

[45] *Id.* at PDF 13.

[46] *Id.* at PDF 103.

it has yet to be shown that analogs lead to better long-term outcomes. Recent work suggests that older human insulins may work as well as newer analog insulins for patients with Type 2 diabetes.

236. Moreover, all insulins at issue in this case have either been available in the same form since the late 1990s or early 2000s or are biologically equivalent to insulins that were available then.

237. As explained in the Journal of the American Medical Association by Dr. Kasia Lipska, an endocrinologist at the Yale School of Medicine and Clinical Investigator at the Yale-New Haven Hospital Center for Outcomes Research and Evaluation:

> We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.[47]

238. Moreover, production costs have decreased in recent years. A September 2018 study in BMJ Global Health calculated that, based on production costs, a reasonable and profitable price for a *one-year supply* of human insulin is between $48 and $71 per person and between $78 and $133 for analog insulin. Another recent study found that the Manufacturers could be profitable charging as little as $2 per

[47] Natalie Shure, *The Insulin Racket,* American Prospect (June 24, 2019), https://prospect.org/health/insulin-racket/ (last visited July 3, 2023).

vial.[48] A third study, based on data collected through 2023, concluded that sustainable cost-based prices "for treatment with insulin in a reusable pen device could cost as little as $96 (human insulin) or $111 (insulin analogues) *per year* for a basal-bolus regimen, $61 *per year* using twice-daily injections of mixed human insulin, and $50 (human insulin) or $72 (insulin analogues) *per year* for a once-daily basal insulin injection (for type 2 diabetes), including the cost of injection devices and needles."[49]

239. Yet, in 2016, diabetics spent an average of $5,705 for insulin. According to a 2020 RAND report, the 2018 list price per vial across all forms of insulin was just $14.40 in Japan, $12.00 in Canada, $11.00 in Germany, $9.08 in France, $7.52 in the United Kingdom, and less than $7.00 in Australia. In the United States it was $98.70.[50]

240. RAND issued an updated report in 2024 using 2022 data. In its report, RAND explained that the gross (or list) price of insulin in the United States had

[48] Gotham D, Barber MJ, Hill A. Production costs and potential prices for biosimilars of human insulin and insulin analogues. BMJ Global Health 2018;3:e000850.

[49] Melissa J. Barber, *et al.*, *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, JAMA Network: Open, Mar. 27, 2024.

[50] *The Astronomical Price of Insulin Hurts American Families*, RAND (Jan. 6, 2021), https://www.rand.org/blog/rand-review/2021/01/the-astronomical-price-of-insulin-hurts-american-families.html (last visited July 15, 2024).

"increased dramatically since the early 2010s in the United States."[51] The report pointed to studies showing that "manufacturer gross prices increased annually by an average of 13 percent from 2007 to 2018," which was "far above general inflation over the same periods."[52]

241. The RAND report also found that insulin prices in the United States far exceeded insulin prices abroad. RAND found that U.S. manufacturer gross prices were 971 percent (or 9.71 times) higher than in the thirty-three countries who belong to the Organisation for Economic Co-operation and Development (OECD) combined.[53] In other words, insulin in the United States was more than nine times higher than in thirty-three middle- to high-income comparison countries.[54] Once rebates and other discounts were applied, net prices in the United States remained 2.33 times higher than in the OECD countries.[55] The gross price is the price paid by patients who are uninsured, in the deductible phase of their plan, or otherwise paying out-of-pocket for insulin.[56]

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[51] Andrew W. Mulcahy, Daniel Schwam, *Comparing Insulin Prices in the United States to Other Countries*, RAND Corporation at 1.

[52] *Id.*

[53] *Id.* at v, 22, 30.

[54] *Id.*

[55] *Id*. at v, 28, 30.

[56] *Id*. at vi.

242. While research and development (also known as R&D) costs often contribute significantly to the price of a drug, the initial basic insulin research—original drug discovery and patient trials—occurred 100 years ago and those costs have long since been recouped. Even more recent costs, such as developing the recombinant DNA fermentation process and the creation of insulin analogs, were incurred decades ago. In recent years, the lion's share of R&D costs is incurred in connection with the development of new insulin-related devices and equipment, not in connection with the drug formulations themselves.

243. The House Committee on Oversight and Reform also found that R&D costs "d[id] not justify price increases." According to the committee, "when drug companies did invest in R&D, those expenditures often went to research designed to protect existing market monopolies." The committee also found that "drug companies often invested in development only after other research—much of it federally funded—demonstrated a high likelihood of financial success."

244. In response to rising scrutiny, the Manufacturer Defendants recently announced limited pricing changes and out-of-pocket limits. On March 1, 2023, Eli Lilly announced that it would reduce the prices of certain insulin medications, capping those prices at $35 per month, with additional reductions to follow later in the year. Specifically, Eli Lilly promised that it would list its Lispro injection at $25 per vial effective May 1, 2023, and slash the price of its Humalog and Humulin

injections by 70% starting in the fourth quarter of 2023. The price reductions to date are limited to these medications and do not apply to other Eli Lilly diabetes medications like Trulicity and Basaglar. These decisions suggest that, prior to March 1, 2023, the prices of these medications had not been raised to cover costs of research and development, manufacture, distribution, or any other necessary expense.

245. Two weeks later, on March 14, 2023, Novo Nordisk announced that it would lower the U.S. list prices of several insulin products by up to 75%—specifically, Levemir, Novolin, NovoLog, and NovoLog Mix 70/30. Novo Nordisk will also reduce the list price of unbranded biologics to match the lowered price of each respective branded insulin. The price reductions to date are limited to these medications and do not apply to other Novo Nordisk diabetes medications like Victoza and Ozempic. These changes will go into effect on January 1, 2024, and, as with Eli Lilly's price reduction, suggest that the prices of these medications before that date were not increased to cover costs of research and development, manufacture, distribution, or any other necessary expense.

246. Two days later, on March 16, 2023, Sanofi followed suit and announced that it would also cap the out-of-pocket cost of its most popular insulin, Lantus, at $35 per month for people with private insurance, effective January 1, 2024, and lower the list price of Lantus by 78% and Apidra, its short-acting insulin, by 70%. Sanofi already capped the price of Lantus at $35 for patients without insurance. The

price reductions to date are limited to these medications and do not apply to other Sanofi diabetes medications like Toujeo and Soliqua. Sanofi's decisions, like Eli Lilly's and Novo Nordisk's, suggest that the prices of Sanofi's medications before January 1, 2024, were not raised to cover costs of research and development, manufacture, distribution, or any other necessary expense.

247. These three announcements ("Price Cuts") are prospective and do not mitigate damages already incurred by payors like Plaintiff.

248. The Price Cuts are limited to certain insulin medications, and do not encompass all at-issue medications. As part of the Insulin Pricing Scheme, PBMs provide preferred formulary placement to the most expensive insulins based on list prices. Accordingly, the Insulin Pricing Scheme will proceed, with the PBMs continuing to target the most expensive at-issue medications, which will likely be the at-issue medications not included in the Price Cuts.

249. The Price Cuts are woefully insufficient. An Eli Lilly spokeswoman has represented that the current list price for a 10-milliliter vial of the fast-acting, mealtime insulin Humalog will drop to $66.40 from $274.70, and a 10-milliliter vial of Humulin will fall from $148.70 to $44.61.[57] These prices far exceed the

[57] Tom Murphy, *Lilly plans to slash some insulin prices, expand cost cap*, AP News (Mar. 2, 2023) (available at https://apnews.com/article/insulin-diabetes-humalog-humulin-prescription-drugs-eli-lilly-lantus-419db92bfe554894bdc9c7463f2f3183).

Manufacturer Defendants' costs and remain significantly higher than the prices for the same and similar drugs in other countries.

250. To make matters worse, on November 8, 2023, before the 65% price cut for its long-acting insulin Levemir had taken effect, Novo Nordisk announced that it would be discontinuing Levemir in the United States, citing manufacturing constraints, formulary-placement issues, and "alternative treatments" for patients. Levemir is the only branded, long-acting insulin product for which Novo Nordisk announced a list price reduction and the only long-acting insulin FDA-approved for pregnancy. Yet, Novo Nordisk is discontinuing Levemir—before allowing the price reduction to take effect—with supply disruptions beginning in early 2024, followed by formal discontinuation of the Levemir FlexPen vial by the end of 2024.

4. Insulin Adjuncts: Type 2 Medications

251. Over the past fifteen years, the Manufacturer Defendants have released several non-insulin medications that help control insulin levels. In 2010, Novo Nordisk released Victoza, and over the next seven years Eli Lilly released Trulicity, Sanofi released Soliqua, and Novo Nordisk followed up with Ozempic.[58] In 2022, Eli Lilly received approval for another GLP-1, Mounjaro. Each can be used in conjunction with insulins to control diabetes.

[58] Victoza, Trulicity, and Ozempic are glucagon-like peptide-1 receptor agonists ("GLP-1") and mimic the GLP-1 hormone produced in the body. Soliqua is a combination long-acting insulin and GLP-1 drug.

252. The Manufacturers negotiate rebates and other fees with the PBMs for "bundles" of insulin and GLP-1 receptor agonist (GLP-1) medications, packaging them as a single class of diabetes medications. This practice is known as "bundling."

253. The Manufacturer Defendants bundle medications to gain formulary access for multiple drugs in exchange for increased manufacturer payments to the PBMs.

254. In 2013, Novo Nordisk tied its "exclusive" rebates for insulin to formulary access for GLP-1 medication, Victoza. The exclusive rebates of 57.5% for Novolin, Novolog, and Novolog Mix 70/30 were more than three times higher than the 18% rebate for plans that included two insulin products on their formulary. In order to qualify for the exclusive rebate, the plans would also need to list Victoza on their formulary, exclude all competing insulin products, and ensure existing patients switch from competitor diabetes medications.[59]

255. Upon information and belief, all Manufacturer Defendants negotiate the prices of insulin and GLP-1 medications through bundling.

256. The first GLP-1 was approved by the FDA in 2005 and was indicated for the treatment of Type 2 diabetes. Currently, the GLP-1 market is consolidated among a limited number of patent-holding entities, with Manufacturer Defendants Eli Lilly, Novo Nordisk, and Sanofi controlling much of this market.

[59] Senate Insulin Report at 78, 79.

257. Through extensive patents and regulatory exclusivities, the Manufacturer Defendants have effectively barricaded competition from the GLP-1 market, giving them the ability to exercise comprehensive control over the price of GLP-1 medications.

258. To date, no generic alternative exists for any GLP-1 medication. The Manufacturer Defendants will continue to enjoy patent protection of their respective GLP-1 agonist molecules through at least 2030, if not later.[60]

259. Novo Nordisk developed and sells three GLP-1 drugs indicated for Type 2 diabetes: Victoza (liraglutide), Xultophy (insulin degludec/liraglutide), and Ozempic (semaglutide). Novo Nordisk holds sixty-two patents related to semaglutide and liragutide, forty-six of which are device patents unrelated to the therapeutic molecule of the GLP-1.[61]

260. Eli Lilly developed and sells two GLP-1 drugs indicated for Type 2 diabetes: Trulicity (dulaglutide) and Mounjaro (tirzepatide/GIP). Eli Lilly holds eighteen patents related to dulaglutide and tirzepatide. Of the four patents related to tirzepatide, two are device patents unrelated to the therapeutic molecule of the

[60] Rasha Alhiary, *et al.*, *Patents and Regulatory Exclusivities on GLP-1 Receptor Agonists*, J. OF THE AM. MED. ASS'N, Vol. 33o, at 650-57 (2023).

[61] Rasha Alhiary, *et al.*, *Delivery Device Patents on GLP-1 Receptor Agonists*, J. OF THE AM. MED. ASS'N, Vol. 331, at 794-796 (2024).

GLP-1. Eli Lilly has applied for seventy-eight patents related to dulaglutide, seventeen of which have been granted to date.[62]

261. Sanofi developed Adylxin (lixisenatide) and Soliqua (insulin glargine/lixisenatide) but currently only sells Soliqua in the United States. Sanofi holds forty-two patents related to lixisenatide, twenty-nine of which are device patents unrelated to the therapeutic molecule of the GLP-1.[63]

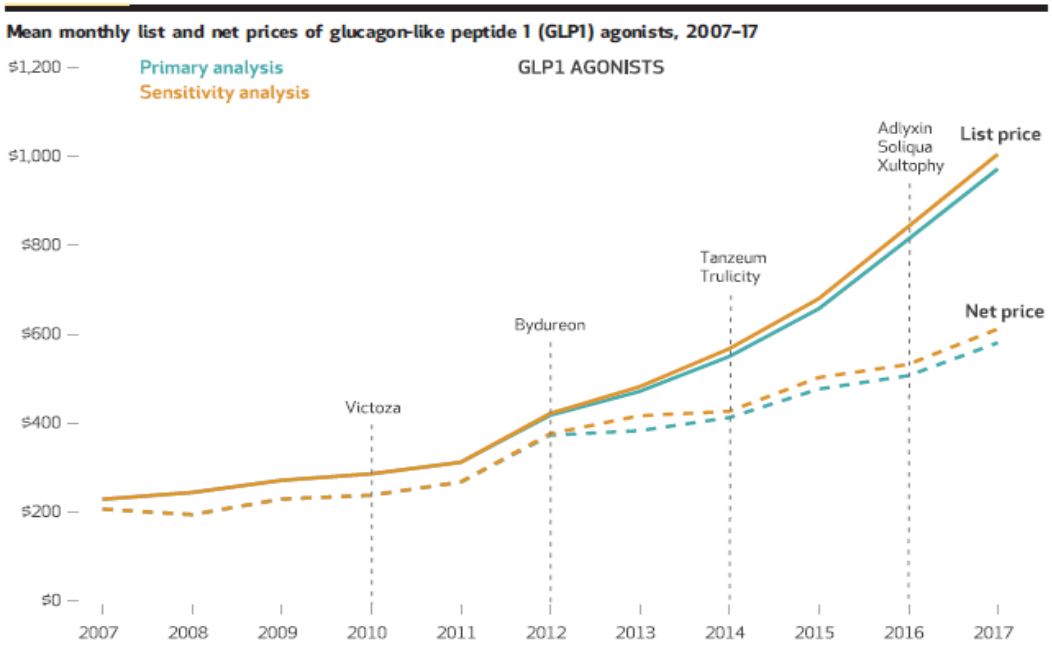
262. This patent stacking and evergreening ensures that generic and other branded GLP-1 cannot enter the market and gives Novo Nordisk, Eli Lilly, and Sanofi disproportionate pricing power over GLP-1 medications.

263. In addition to the limited competition in the GLP-1 landscape, the Manufacturer and PBM Defendants use this disproportionate pricing power to inflate the prices of GLP-1s, consistent with the broader Insulin Pricing Scheme.

[62] *Id.*

[63] *Id.*

Figure 3: List and net prices of GLP-1 agonists



264. As shown above, counterintuitively, list and net prices increased as more GLP-1 medications were approved and introduced. Between 2007 and 2017, the average list price of GLP-1s rose 15% per year despite the introduction of competing brands. The net price increased an average of 10% per year during the same time period.[64]

265. The PBM Defendants are also central to these untethered price increases. As shown in the chart above, the growing disconnect between the list and net prices of these drugs further reflects the PBM Defendants' ill-gotten gains through identical methods to those employed in the Insulin Pricing Scheme.

[64] Ameet Sarpatwari, *et al.*, *Diabetes Drugs: List Price Increases Were Not Always Reflected In Net Price; Impact Of Brand Competition Unclear*, HEALTH AFFAIRS, Vol. 40, at 772-78 (2021).

266. The absence of generics in the GLP-1 market allows manufacturers to keep prices artificially high. PBMs then realize the benefit of these artificially high prices through manufacturer payments in exchange for formulary placement. PBMs and manufacturers are thus incentivized to increase prices or maintain high, untethered prices for GLP-1s.

267. GLP-1s are significantly more expensive in the United States than in other countries, indicating that the increasing price of GLP-1s are untethered to any legal, competitive, or fair market price. For example, in 2023, the list price for a one-month supply of Ozempic was about $936 in the United States, $147 in Canada, $103 in Germany, $93 in the United Kingdom, $87 in Australia, and $83 in France.

268. In 2018, Victoza's list price in the United States was more than double its average list price in eleven comparable countries and Trulicity's list price in the United States was more than six times its average list price in eleven comparable countries. One study found that drug companies could profitably sell certain GLP-1s, including Ozempic, for $0.89-$4.73 per month.

269. In March 2024, PBM Defendant Evernorth entered into a financial guarantee agreement for GLP-1 spend with Manufacturer Defendants Novo Nordisk and Eli Lilly to limit the annual cost increase of GLP-1s to 15%.[65]

270. Like the caps put in place for insulins, Evernorth, Eli Lilly, and Novo Nordisk's agreement suggests that the prices of GLP-1s before March 2024 were not raised to cover costs of research and development, manufacture, distribution, or any other necessary expense. Such cost caps and savings guarantees indicate that the increasing price of GLP-1s were untethered to any legal, competitive, or fair market price. Further, this agreement is prospective and does not mitigate damages already incurred by payors like Plaintiff.

271. The following is a list of diabetes medications at issue in this lawsuit:

[65] Evernorth Health Services, Mar. 7, 2024, https://www.evernorth.com/articles/evernorth-announces-industry-first-financial-guarantee-glp-1-spend

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Human	*Rapid-Acting*	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R 500	Eli Lilly	1982	$1784 (vial) $689 (pens)
		Novolin R	Novo Nordisk	1991	$165 (vial) $312 (pens)
	Intermediate	Humulin N	Eli Lilly	1982	$178 (vial) $566 (pens)
		Humulin 70/30	Eli Lilly	1989	$178 (vial) $566 (pens)
		Novolin N	Novo Nordisk	1991	$165 (vial) $312 (pens)
		Novolin 70/30	Novo Nordisk	1991	$165 (vial) $312 (pens)
Analog	*Rapid-Acting*	Humalag	Eli Lilly	1996	$342 (vial) $636 (pens)
		Novolog	Novo Nordisk	2000	$347 (vial) $671 (pens)
		Apidra	Sanofi	2004	$341 (vial) $658 (pens)
	Long-Acting	Lantus	Sanofi	2000	$340 (vial) $510 (pens)
		Levemir	Novo Nordisk	2005	$370 (vial) $555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	$466 (pens) $622 (max pens)

		Tresiba	Novo Nordisk	2015	$407 (vial) $610 (pens – 100u) $732 (pens – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	$1013 (pens)
		Victoza	Novo Nordisk	2010	$813 (2 pens) $1220 (3 pens)
		Ozempic	Novo Nordisk	2017	$1022 (pens)
		Soliqua	Sanofi	2016	$928 (pens)

B. The Dramatic Rise in the Prices of Diabetes Medications in the United States

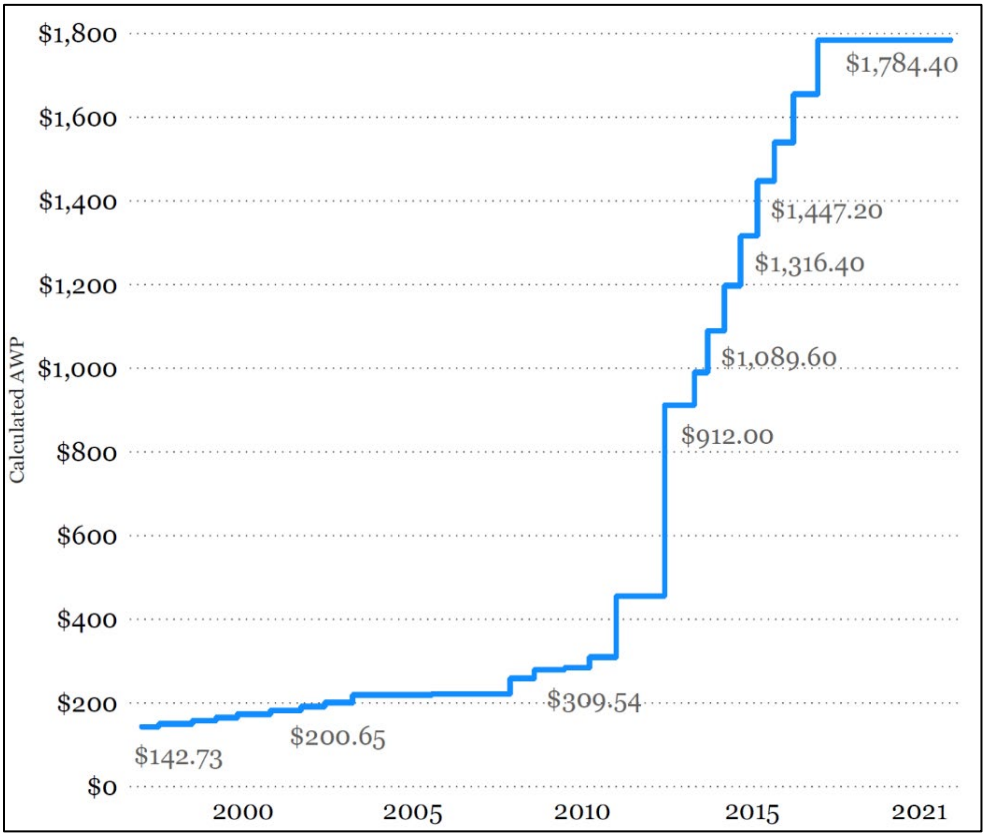
272. Over the past 25 years, the list price of certain insulins has increased in some cases by more than 1000% (10x).

273. According to the U.S. Bureau of Labor Statistics, $165 worth of consumer goods and services in 1997 dollars would, in 2021, have cost $289 (1.75x).[66]

274. Since 1997, Eli Lilly has raised the list price of a vial of Humulin R (500U/mL) from $165 to $1784 in 2021 (10.8x).

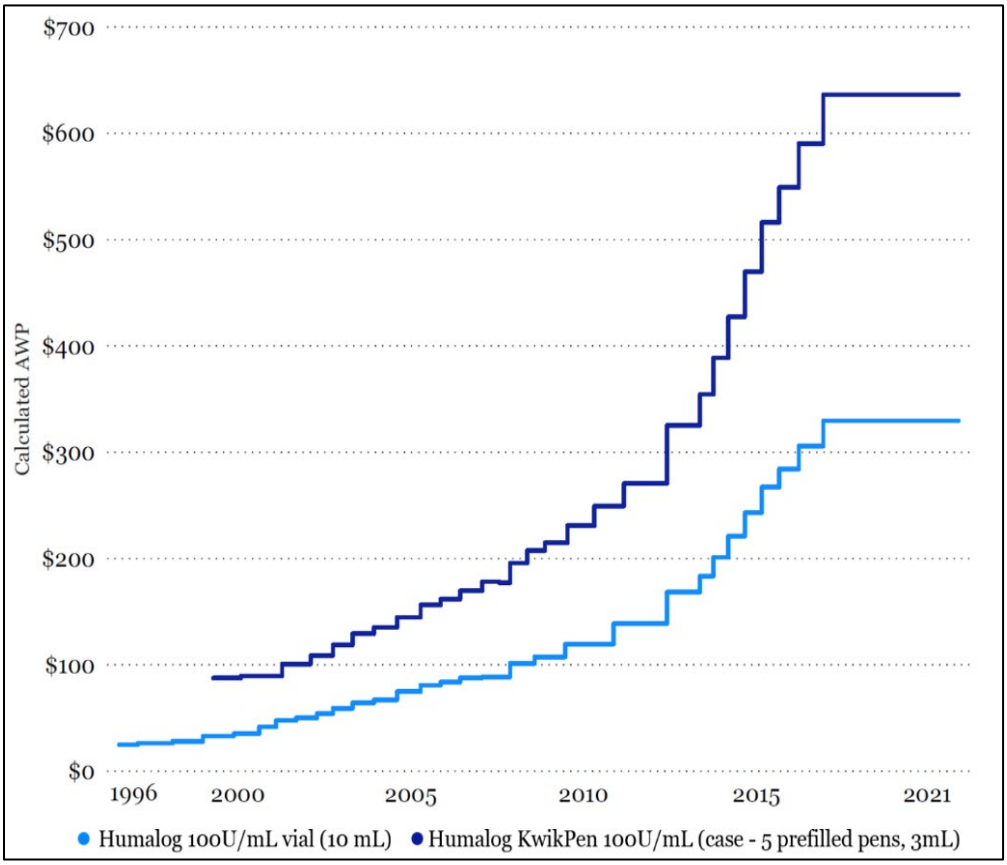
[66] https://www.bls.gov/data/inflation_calculator.htm (last visited July 3, 2023). The Consumer Price Index (CPI) measures "the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services." (https://www.bls.gov/cpi/).

Figure 4: Rising list prices of Humulin R (500U/mL) from 1997-2021



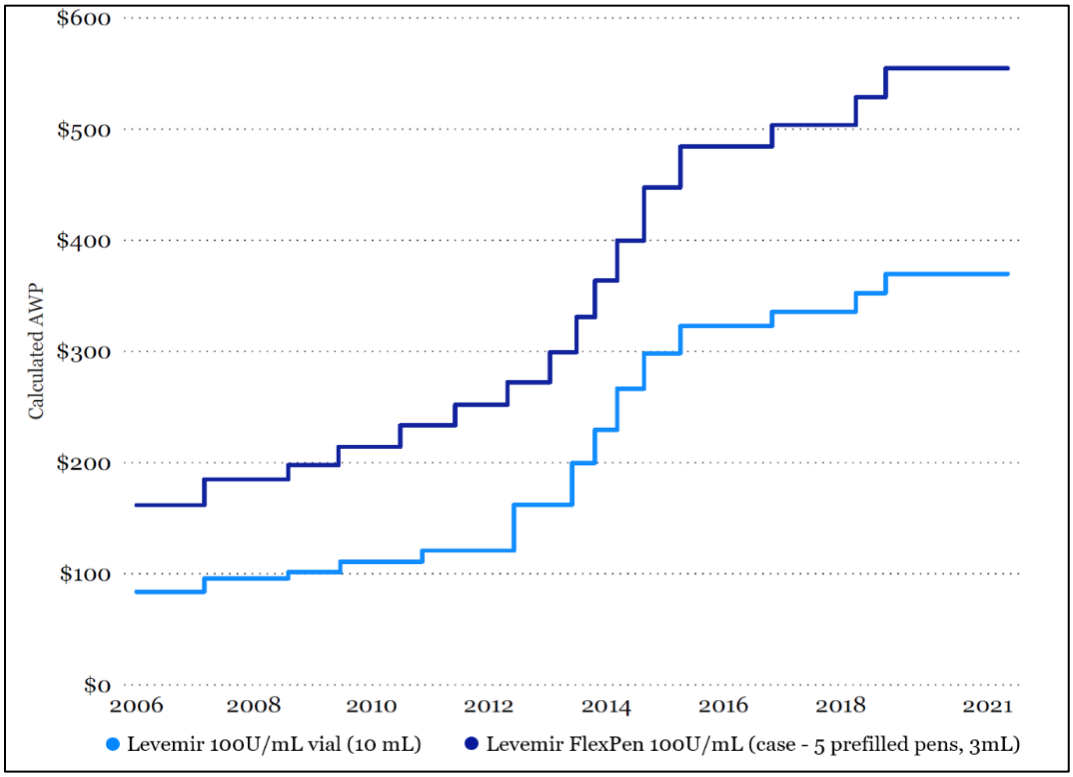
275. Since 1996, Eli Lilly has raised the price for a package of pens of Humalog from under $100 to $663 (6.6x) and from less than $50 per vial to $342 (6.8x). (See Figure 5 below.)

Figure 5: Rising list prices of Humalog vials and pens from 1996-2021



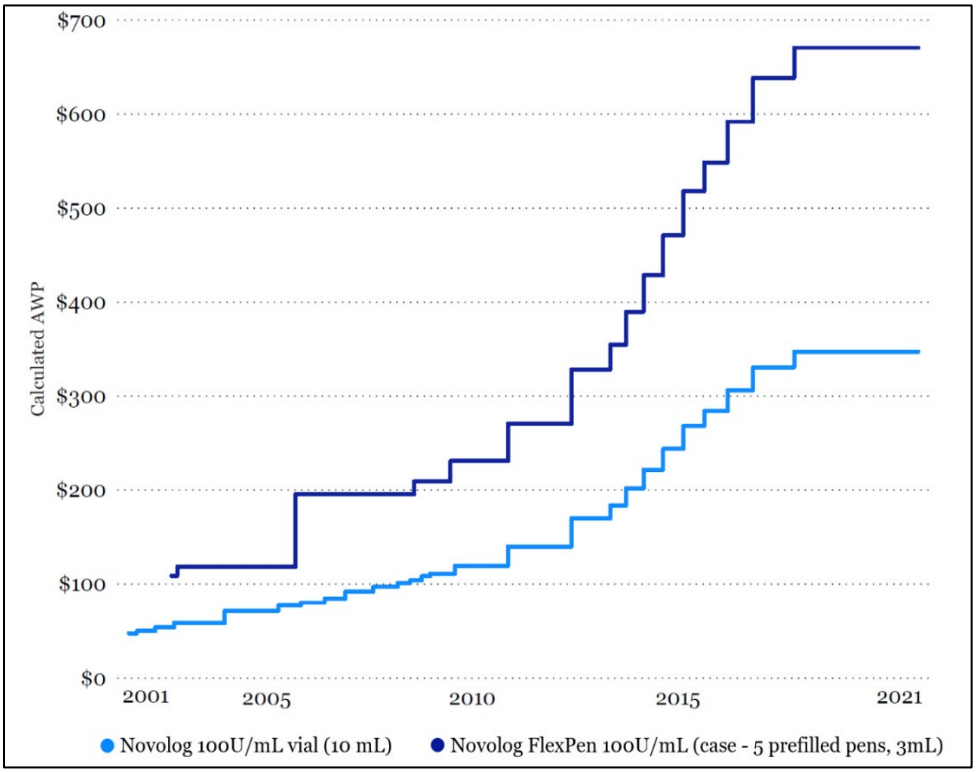
276. From 2006 to 2020, Novo Nordisk raised the price of Levemir from $162 to $555 (3.4x) for pens and from under $100 to $370 per vial (3.7x).

Figure 6: Rising list prices of Levemir from 2006-2021



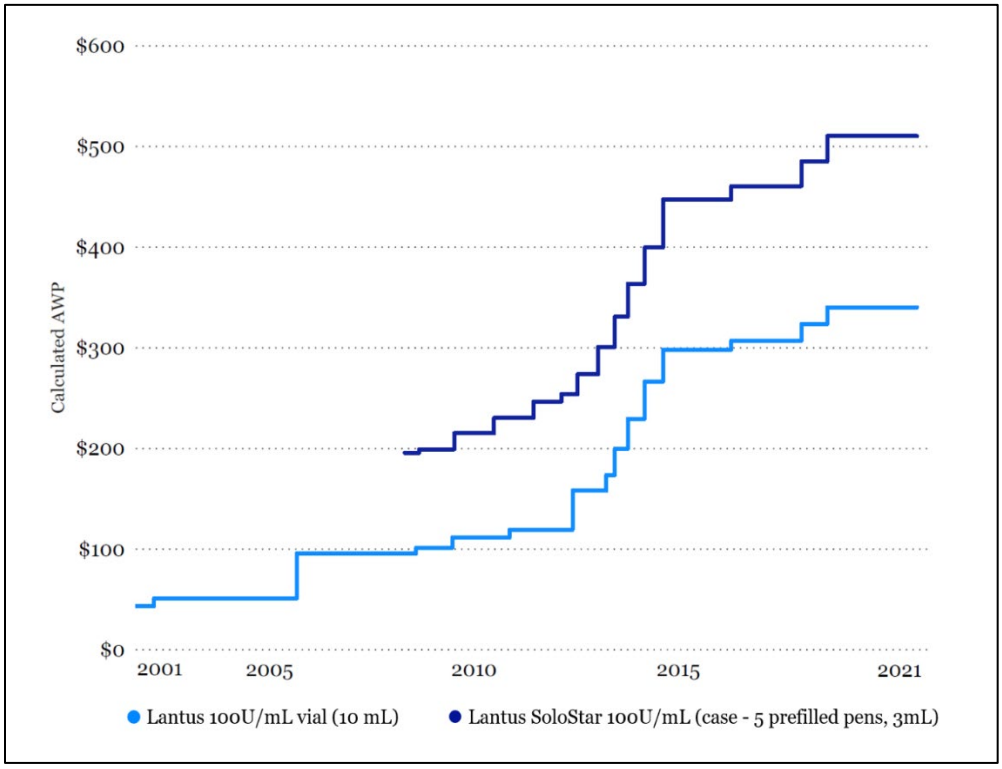
277. From 2002 to 2021, Novo Nordisk raised the list price of Novolog from $108 to $671 (6.2x) for a package of pens and from less than $50 to $347 (6.9x) per vial.

Figure 7: Rising list prices of Novolog vials and pens from 2002-2021



278. Sanofi has kept pace as well. It manufactures a top-selling analog insulin—Lantus—which has been and remains a flagship brand for Sanofi. It has been widely prescribed nationally and within the Commonwealth of Virginia, including to Plaintiff's Plan Participants. Sanofi has raised the list prices for Lantus from less than $200 in 2006, to over $500 in 2020 (2.5x) for a package of pens and from less than $50 to $340 per vial (6.8x). (See Figure 8 below.)

Figure 8: Rising list prices of Lantus vials and pens from 2001-2021



279. The Manufacturer Defendants have similarly increased prices for non-insulin diabetes medications.

280. Driven by these price hikes, payors' and diabetics' spending on these drugs has drastically increased with totals in the tens of billions of dollars.

281. The timing of the price increases reveals that the Manufacturer Defendants have not only dramatically increased prices for the at-issue diabetes treatments but have done so in lockstep.

282. Between 2009 and 2015, for example, Sanofi and Novo Nordisk raised the list prices of their insulins in tandem 13 times, taking the same price increase

down to the decimal point within days of each other (sometimes within a few hours).[67]

283. This practice, in which competitors communicate their intention not to price-compete against one another, is known as "shadow pricing."

284. In 2016, Novo Nordisk and Sanofi's lockstep increases for the at-issue drugs represented the highest drug price increases in the pharmaceutical industry.

285. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 9 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 10 demonstrates this behavior with respect to Novolog and Humalog.

[67] Senate Insulin Report at 53-54.

Figure 9: Rising list prices of long-acting insulins

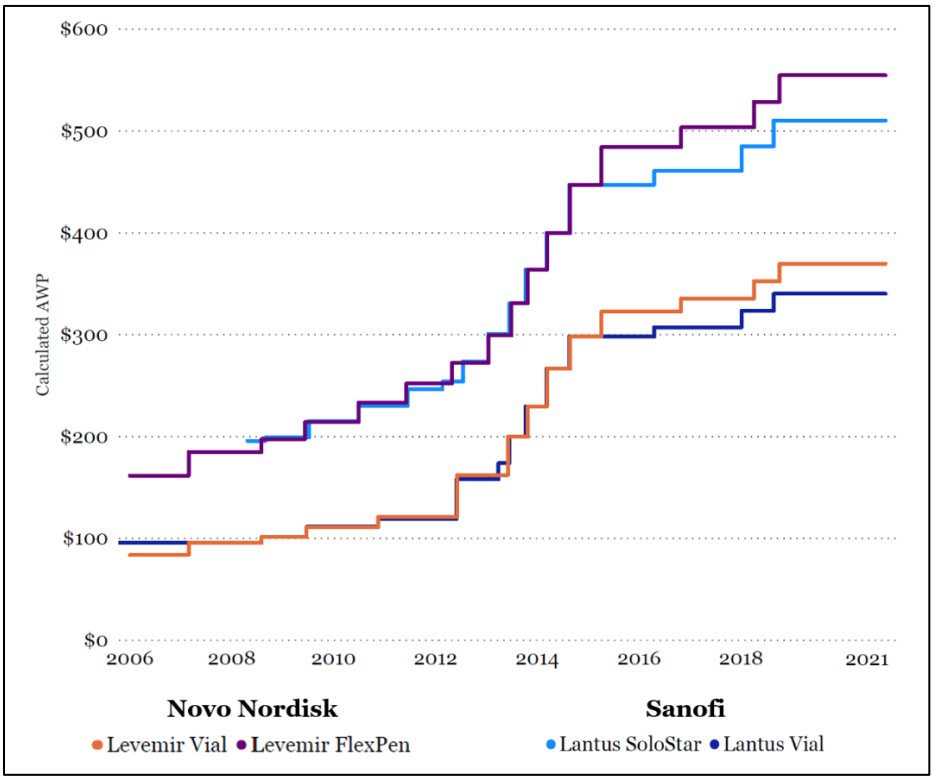
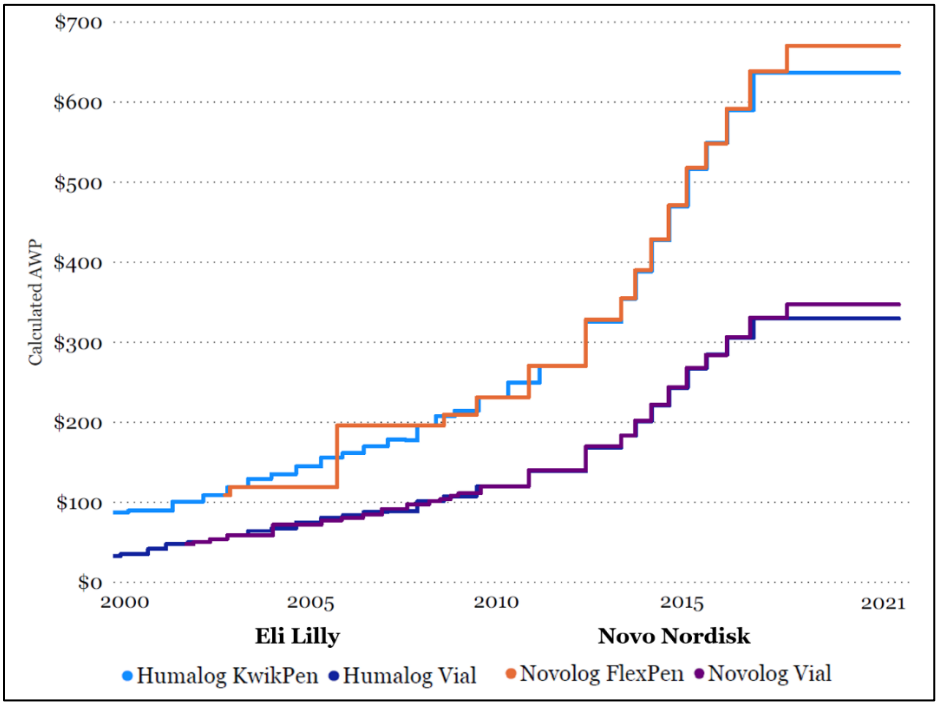
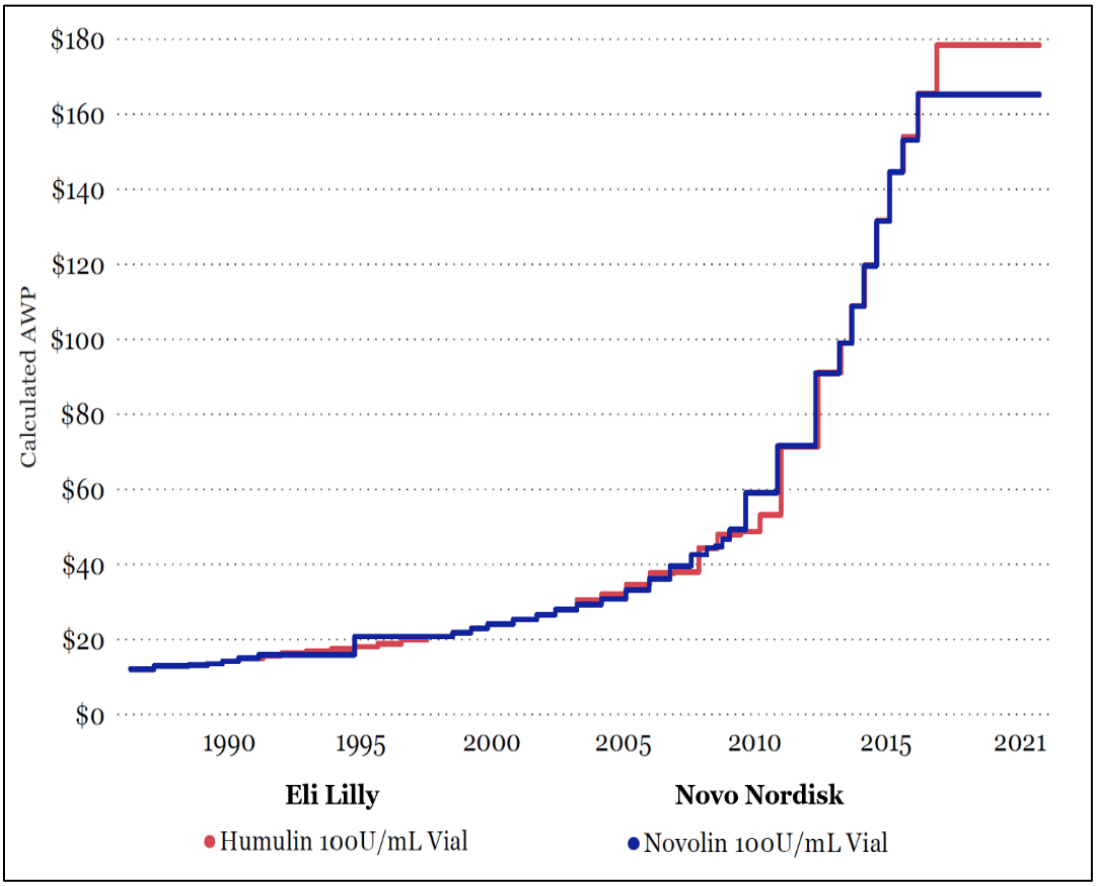


Figure 10: Rising list prices of rapid-acting insulins



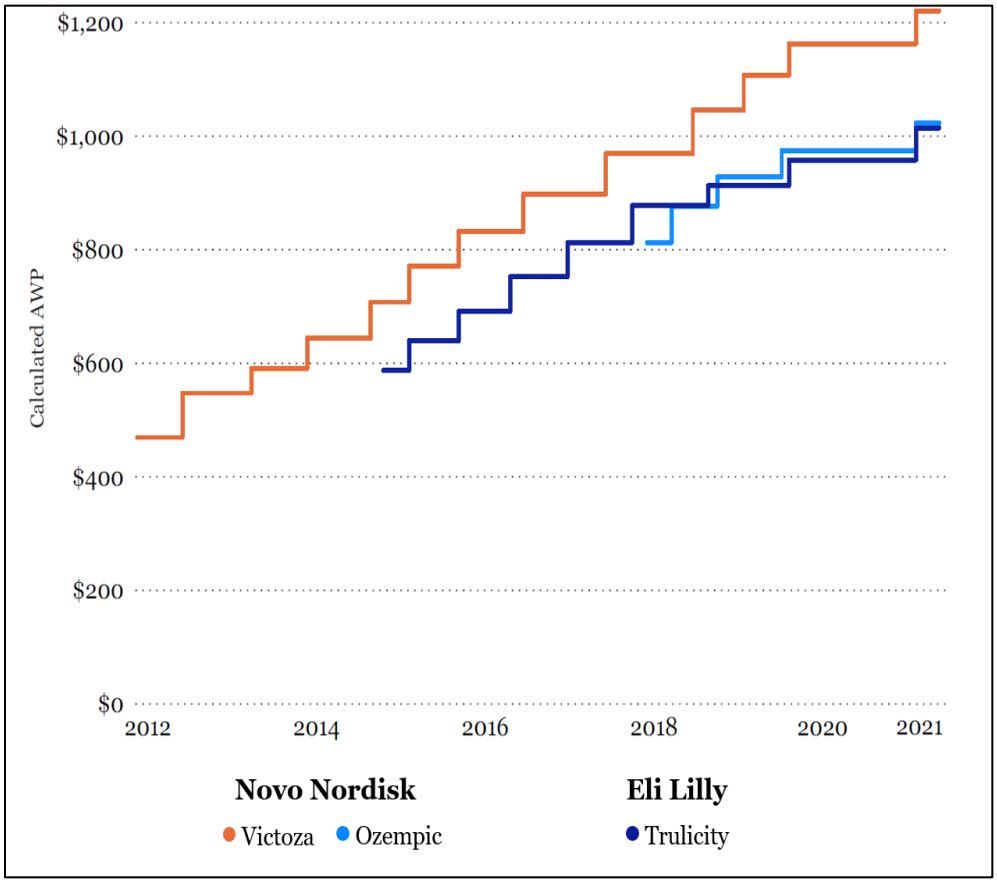
286. Figure 11 below demonstrates this behavior with respect to the human insulins—Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 11: Rising list price increases for human insulins



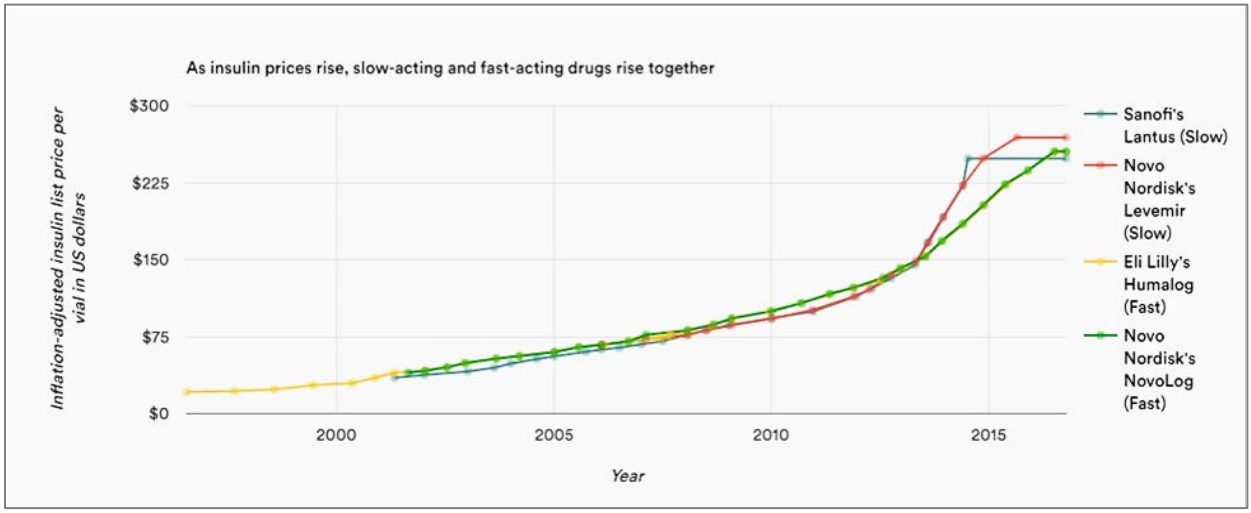
287. Figure 12 below demonstrates Novo Nordisk and Eli Lilly's lockstep price increases for their Type-2 drugs Trulicity, Victoza, and Ozempic.

Figure 12: Rising list prices of Type 2 drugs



288. Figure 13 below shows how, collectively, the Manufacturer Defendants have exponentially raised the prices of insulin products in near-perfect unison.

Figure 13: Lockstep insulin price increases



289. There is clear evidence that these lockstep price increases were carefully coordinated to preserve formulary placement for the at-issue medications and to allow greater rebates to the PBMs, and further illustrate the perverse economics of competing by increasing prices in lockstep.

290. Evidence clearly shows that Eli Lilly was not inclined to lower prices of its insulin products to compete with the other drug makers. Documents produced to the House Committee on Oversight and Reform[68] show that executives at Eli Lilly regularly monitored competitors' pricing activity and viewed competitors' price increases as justification to raise the prices of their own products. On May 30, 2014, a senior vice president at Eli Lilly sent a proposal to Enrique Conterno—then-

[68] Drug Pricing Investigation at PDF 162.

President of Lilly Diabetes—for a June 2014 price increase on Humalog and related product Humulin. The executive reported that the company had learned that Novo Nordisk had just executed a 9.9% price increase across its insulin portfolio. Mr. Conterno remarked, "While the list price increase is higher than we had planned, I believe it makes sense from a competitive perspective." Eli Lilly took a 9.9% price increase shortly thereafter, on June 5, 2014.

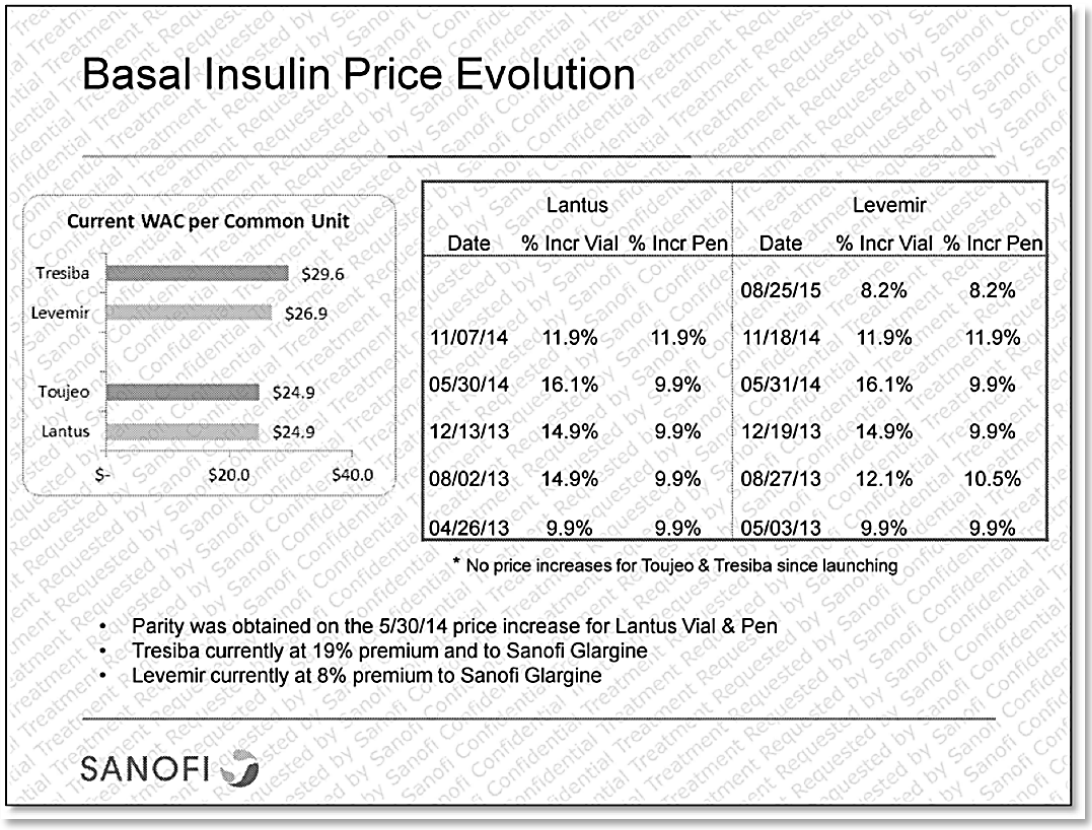
291. Six months later, on November 19, 2014, Mr. Conterno reported to then-CEO John Lechleiter that Novo Nordisk had just taken another 9.9% price increase on NovoLog—the direct competitor to Eli Lilly's Humalog. Mr. Conterno wrote, "[a]s you are aware, we have assumed as part of our business plan a price increase of 9.9% for Humalog before the end of the year." The following Monday—six days after Mr. Conterno's initial email to the CEO—Eli Lilly took price increases of 9.9% on all of its Humalog and Humulin products.

292. Sanofi also closely monitored competitors' pricing activity and planned its own pricing decisions around price increases by Eli Lilly and Novo Nordisk. Executives were aware that Sanofi's long-acting insulin competitors—particularly Novo Nordisk—would likely match its pricing actions on long-acting insulin. In internal documents, Sanofi leaders welcomed price increases on competitors' products because they allowed the company to claim it was maintaining pricing "parity" with competitors.

293. Sanofi clearly had no incentive or intention to compete to lower its insulin pricing. For example, on November 7, 2014, Sanofi executed a price increase of approximately 12% across its family of Lantus products. The following week, a Sanofi senior vice president sent an email asking, "[d]id Novo increase the price of Levemir following our price increase on Lantus last week? I just want to confirm we can still say that Lantus and Levemir are still priced at parity on a WAC [wholesale acquisition cost] basis." The head of Sanofi pricing responded that Novo had not yet taken the price increase, but noted, "[o]ver the past four price increases on Lantus they have typically followed within 1 month." Novo Nordisk raised the price of Levemir by 12% the following week.

294. An internal Sanofi chart shows that, between April 2013 and November 2014, it had carefully tracked that each time it raised the price of Lantus, Novo Nordisk quickly followed suit to match its price increases for Levemir:

Figure 14: Sanofi price-tracking



295. It also is clear that the Manufacturers often used a competitor's price increases as a justification for their own increases. For example, before taking price increases on Lantus, Sanofi compared the new list price to the prices of competitor products. In an April 2018 email exchange about accelerating and increasing previously planned price increases for Lantus and Toujeo (from July to April, and from 3% on Lantus to 5.3%), one senior director requested, "[p]lease confirm how the new WAC of Lantus/Toujeo would compare with the WAC of Levemir/Tresiba." In reply, another senior Sanofi leader provided a chart comparing Sanofi prices to those of its competition.

296. Sanofi also engaged in shadow pricing with its rapid-acting insulin products, including Apidra. Sanofi was not the market leader in the fast-acting insulin space and typically did not act first to raise prices. However, when its competitors raised prices on their fast-acting insulins, Sanofi quickly followed suit. As a Sanofi slide deck explained, "Over the past three years, we have executed a 'fast follower' strategy for Apidra and have executed price increases only after a price increase was announced."

297. In December 2018, Sanofi's director of strategic pricing and planning emailed diabetes and cardiovascular pricing committee members seeking approval for across-the-board price increases for its rapid- and long-acting insulin products, including Lantus, Toujeo, and Apidra. The then-Senior Vice President and Head of Sanofi's North America General Medicines group forwarded the proposal to the then-Senior Vice President and Head of Sanofi's External Affairs and inquired, "[p]rior to my approval, just confirming that we are still on for these." The Head of Sanofi's External Affairs wrote back, "[y]es. As of now I don't see any alternative. Not taking an increase won't solve the broader policy/political issues, and based on intel, believe many other manufacturers plan to take increases next year as well." He added, "[s]o while doing it comes with high political risk, I don't see any political upside to not doing it."

298. Although Sanofi generally led price increases in the long-acting insulin market with its pricing for Lantus, Novo Nordisk often led in the rapid-acting market with NovoLog. On May 8, 2017, Novo Nordisk CEO Lars Jorgenson learned that Eli Lilly had raised U.S. list prices by approximately 8% across its injectable diabetes drug portfolio. Mr. Jorgenson emailed this information to a Novo Nordisk executive and asked, "[w]hat is our price increase strategy?" The executive responded, "LLY [Eli Lilly] followed our increase on NovoLog, so we're at parity here, so no action from us. They led with Trulicity and based on our strategy, we will follow which will likely be on June or July 1st."

299. Further illustrating the anti-competitive scheme between the Manufacturers, rather than compete by lowering prices, Sanofi raised Lantus's list price to respond to rebate and discount competition from Novo Nordisk. Novo Nordisk manufactures two long-acting insulins under the trade names Levemir and Tresiba, as well as two rapid-acting insulins NovoLog and Fiasp. In the long-acting insulin category, Lantus and Levemir often compete to win the same accounts. According to internal memoranda, in 2013, Sanofi believed that Novo Nordisk was attempting to minimize the clinical difference between Lantus and Levemir and was offering "increased rebates and/or portfolio offers for the sole purpose of removing Lantus from favorable formulary access." According to an internal Sanofi memo, "the strategy to close the price differential between the Lantus vial and pen before

the LOE [loss of exclusivity] period was believed to be critical to the overall long-term success of the franchise."

300. At the time Sanofi faced increased pressure from its payor and PBM clients to offer more generous rebates and price protection terms or face exclusion from formularies, developments that were described as "high risk for our business" that had "quickly become a reality." This market environment created an enormous challenge for Lantus and, in order to protect its flagship diabetes franchise, Sanofi increased Lantus's list price so that it could improve its rebate and discount offering to payors while maintaining net sales.

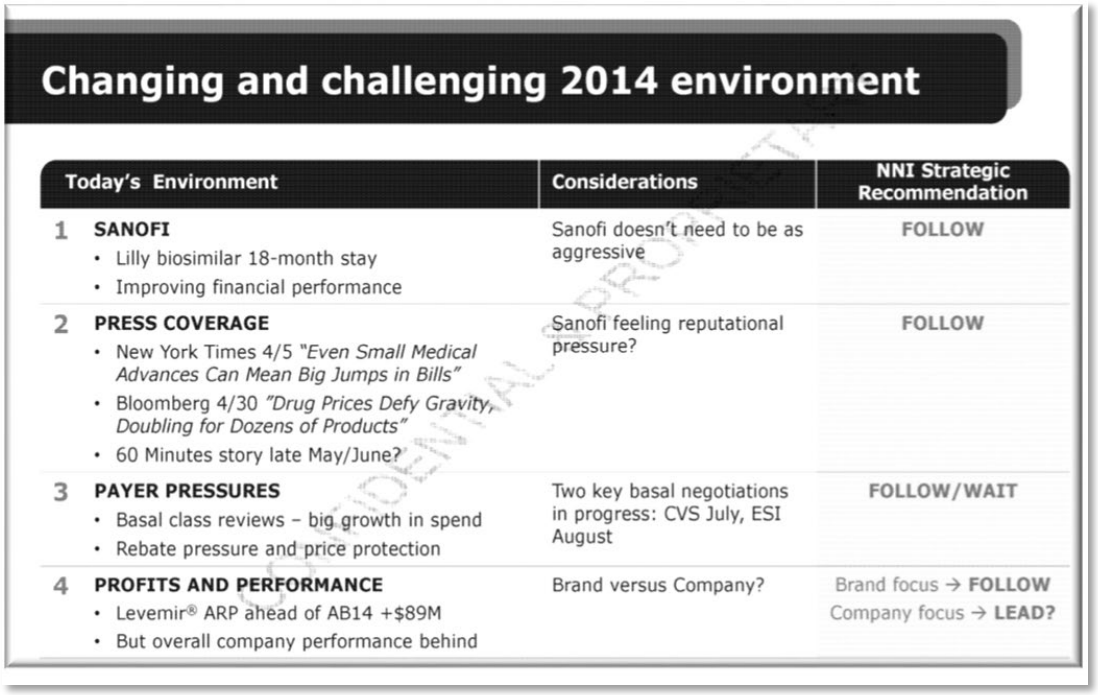
301. Sanofi understood the risk of its decision and "went into 2013 with eyes wide open that the significant price increases planned would inflame [its] customers," and that its aggressive pricing actions would cause an immediate reaction from Novo Nordisk. However, it was seeking to make up for "shortfalls with Lantus demand generation and global profit shortfalls" which it said, "put pressure on the US to continue with the price increases to cover gaps." The company conceded that it was "difficult to determine whether we would face these risks anyway if we hadn't taken the price increases."

302. Novo Nordisk also engaged in shadow pricing with its long-acting insulin, Levemir, for example increasing Levemir's list price in lockstep with Lantus in its continued effort to offer increased rebates and discounts to payors and displace

Lantus from preferred formulary placement. Novo Nordisk typically did not act first to raise prices. However, when its competitors raised prices on their fast-acting insulins, Novo Nordisk followed suit. A March 2015 Novo Nordisk pricing committee presentation slide articulated this strategy: "Levemir price strategy is to follow market leader."

303. On May 19, 2014, Novo Nordisk's pricing committee discussed how to price Levemir in response to Sanofi's 2013 pricing actions. Based on an internal presentation created for this meeting, Novo Nordisk's pricing committee discussed whether it should be a follower in the market, in relation to Sanofi, and considered external factors like press coverage, payor reactions, profits, and performance. In each case, the company's strategic recommendation was to follow Sanofi's pricing moves, rather than lead. Of note, the presentation shows that the pricing committee considered Levemir's performance, which was ahead of 2014's annual budgeting by $89 million, but that "overall company performance [is] behind." The presentation appears to recommend following Sanofi's pricing actions if the brand's performance is the priority, and to lead if the company's performance is the priority. An excerpt of Novo Nordisk's presentation is shown below:

Figure 15: Novo Nordisk pricing committee presentation



Changing and challenging 2014 environment

	Today's Environment	Considerations	NNI Strategic Recommendation
1	**SANOFI** • Lilly biosimilar 18-month stay • Improving financial performance	Sanofi doesn't need to be as aggressive	FOLLOW
2	**PRESS COVERAGE** • New York Times 4/5 *"Even Small Medical Advances Can Mean Big Jumps in Bills"* • Bloomberg 4/30 *"Drug Prices Defy Gravity, Doubling for Dozens of Products"* • 60 Minutes story late May/June?	Sanofi feeling reputational pressure?	FOLLOW
3	**PAYER PRESSURES** • Basal class reviews – big growth in spend • Rebate pressure and price protection	Two key basal negotiations in progress: CVS July, ESI August	FOLLOW/WAIT
4	**PROFITS AND PERFORMANCE** • Levemir® ARP ahead of AB14 +$89M • But overall company performance behind	Brand versus Company?	Brand focus → **FOLLOW** Company focus → **LEAD?**

304. In alignment with this strategy, Novo Nordisk's pricing committee debated potential pricing scenarios based on Sanofi's actions, which they projected with a great deal of specificity. The presentation provided options regarding whether the company should follow Sanofi—and increase list price in July—or lead with a 9.9% increase in August which it considered "optically less aggressive." Based on internal memoranda, Novo Nordisk's pricing committee decided to revisit the issue with specific recommendations once Sanofi took action.

305. Less than two weeks later, on May 30, 2014, Farruq Jafery, Vice President of Pricing, Contract Operations and Reimbursement, emailed Novo Nordisk's pricing committee to inform them that "Sanofi took a price increase on

Lantus effective today: 16.1% vial and 9.9% pen." He further wrote that the pricing committee had "agreed that the best strategy for Levemir is to observe the market and maintain list price parity to competitors." Mr. Jafery then requested that Novo Nordisk's committee vote "ASAP" to raise the list price of Levemir effective May 31, 2014 (the next day) from $191.28 to $222.08 for vials and from $303.12 to $333.12 for pens. Only a few hours after Sanofi took its list price increase, members of the pricing committee approved Mr. Jafery's request and Novo Nordisk moved forward with a 16.1% increase on Levemir vial, and a 9.9% increase on Levemir FlexPen and FlexTouch.

306. Another series of emails shows that Novo Nordisk again shadowed Sanofi's price increase in November 2014, increasing Levemir's list price immediately after Sanofi increased Lantus vials and pens by 11.9%. On the morning of November 7, 2014, Novo Nordisk's pricing committee learned that Sanofi increased Lantus's list price overnight. And, by the afternoon they were asked to approve the same exact price increase for Levemir, which was approved hours later.

307. The speed with which Novo Nordisk reacted to Sanofi's price changes is notable. Within 25 minutes after learning of Sanofi's price increase, Rich DeNunzio, Senior Director of Novo Nordisk's Strategic Pricing, emailed Novo Nordisk's pricing committee to alert them of the change and promise a recommendation the same afternoon after reviewing the financial impact of any

move. By late afternoon, Mr. DeNunzio had requested Novo Nordisk's pricing committee again "follow [Sanofi's] 11.9% [list price increase] on November 18th" and vote to increase Levemir's list price, which was promptly approved by Novo Nordisk's chief financial officer for U.S. operations, Lars Green.

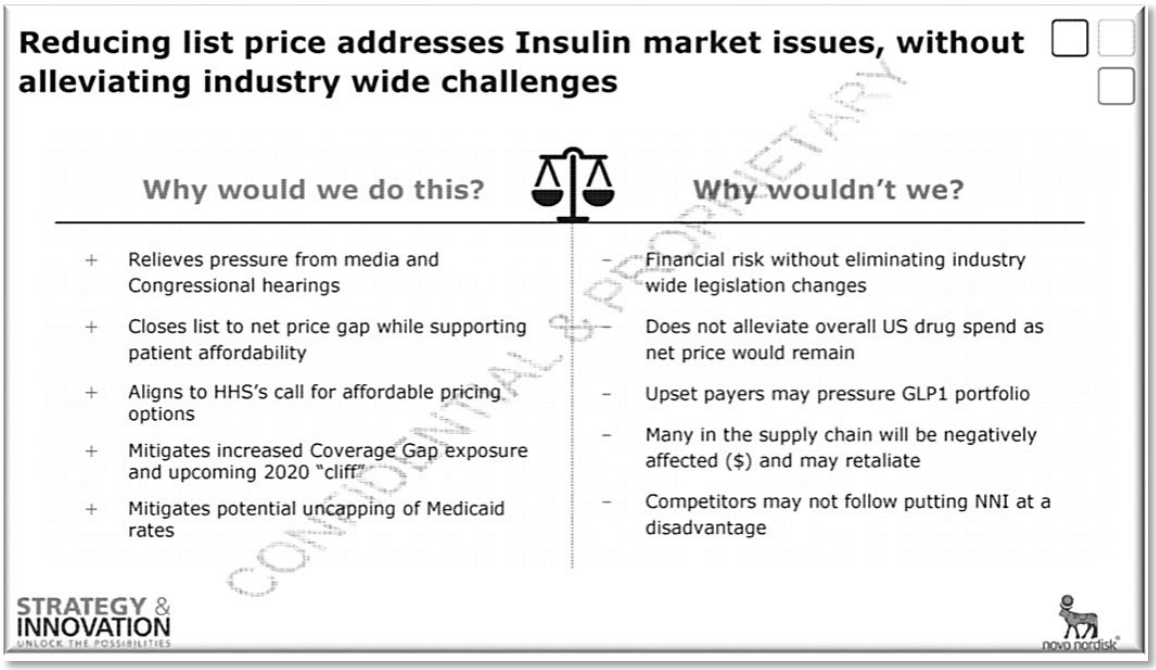
308. Novo Nordisk's pricing strategy for other diabetes products appears to have become the subject of humorous exchanges among senior analysts within the company. After a Novo Nordisk analyst shared news of an Eli Lilly price increase for a diabetes product on December 24, 2015, a senior director of national accounts wrote, "[m]aybe Sanofi will wait until tomorrow morning to announce their price increase ... that's all I want for Christmas." The first analyst responded, "I actually started a drinking game—I have to take a shot for every response that says 'what about Sanofi,'" and then, "[m]y poor liver....'" The senior director responded, "Ho Ho Ho!!!"

309. The back-and-forth between Novo Nordisk officials underscores how closely it was monitoring Sanofi's actions and appears to mirror the approach laid out in a January 27, 2014, presentation regarding the company's bidding strategy that hinged on CVS Caremark's business. Novo Nordisk described its bids for the CVS Caremark business as "pivotal," and laid out a game of cat-and-mouse across different accounts in which company officials sought to have Levemir be the only therapeutic option on different PBM formularies. Novo Nordisk recognized that

offering "attractive exclusive rebates to large, receptive customers" would "encourage a stronger response from Sanofi." However, Novo Nordisk was willing to take this risk because it would result in "immediate volume and value" for the company and could lead to an exclusive deal for CVS's commercial formulary.

310. The agreements the Manufacturers had with the PBM Defendants deterred competition on lowering price. For example, following its April 2018 list price increase, Novo Nordisk began to face pressure from payors, the media, and Congress to reduce the price of its insulin drugs. On May 29, 2018, Novo Nordisk's USPC debated whether it should reduce the list price of its insulin drugs by 50% after a string of news reports detailed how patients were struggling to afford their medications. Novo Nordisk believed that a 50% cut would be a meaningful reduction to patients, significantly narrow the list-to-net gap, head off negative press attention, and reduce "pressure" from Congressional hearings. However, Novo Nordisk was concerned that a list price reduction posed significant financial risk to the company. It is noteworthy that the company's primary concerns were retributive action from other entities in the pharmaceutical supply chain, many of which derive payments that are based on a percentage of a drug's WAC price. A PowerPoint slide created for this meeting suggests the reasons not to lower prices concerns that "many in the supply will be negatively affected ($) and may retaliate" and that its "[c]ompetitors may not follow putting [it] at a disadvantage":

Figure 16: Novo Nordisk presentation on reduced list prices



311. Despite these concerns, internal memoranda suggest that Novo Nordisk was still prepared to lower its list price by 2019 or 2020 if its "must haves" were met, which included an agreement from its payor and PBM clients that they would not retaliate against them by changing their formulary placement and would accept lower rebate percentages.

312. According to internal memoranda, Novo Nordisk's board of directors voted against this strategy in June 2018 and recommended that the company continue its reactive posture. The rationale for this decision was the "$33 million downside identified (NovoLog only)," "risk of payer [PBM] backlash or demand for current rebate on new NDC," and "high likelihood of immediate pressure to take similar action on other products." Following the decision by its board of directors,

on August 30, 2018, Novo Nordisk decided to continue its strategy to "monitor the market . . . to determine if other major pharma companies are taking list price [increases]."

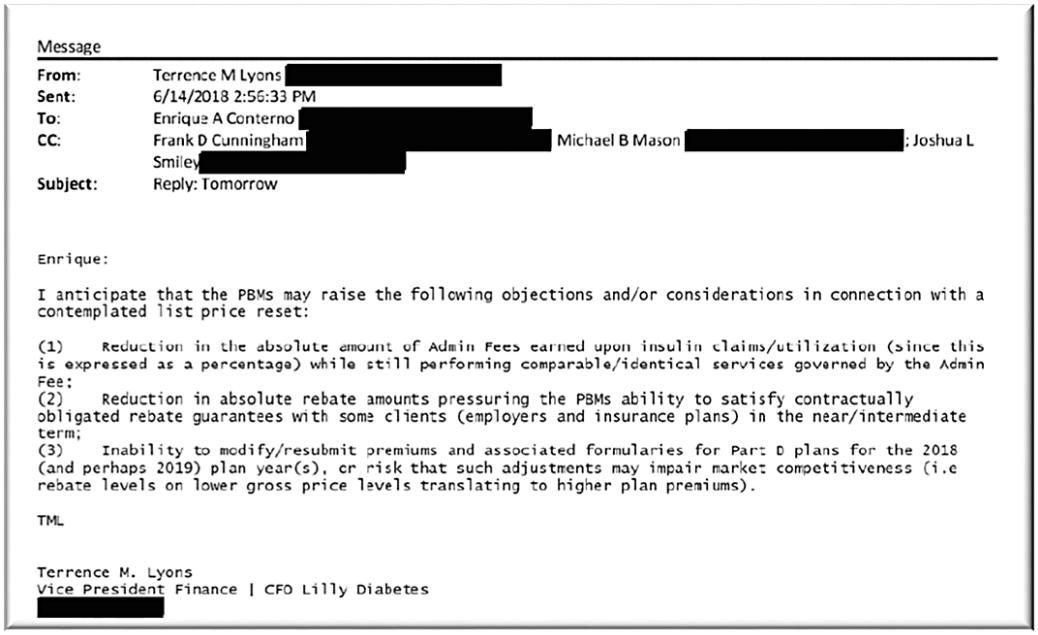
313. Following years of rebate and list price increases, the Manufacturers faced increased pressure from patients, payors, and the Federal government to decrease insulin's WAC price. However, internal memoranda and correspondence suggest that the downstream impact of lowering the WAC prices presented hurdles for pharmaceutical companies.

314. There is also evidence of communications between the Manufacturers and the PBM Defendants regarding lowering the prices of insulins. For example, a June 23, 2018 email memorializes a conversation Eli Lilly's President of the Diabetes Unit, Enrique Conterno, had with the CEO of OptumRx, who allegedly "re-stated that [OptumRx] would be fully supportive of Lilly pursuing a lower list price option," but indicated that OptumRx would encounter challenges, namely, "the difficulty of persuading many of their customers to update contracts without offering a lower net cost to them."

315. In response, an Eli Lilly executive noted, "we wouldn't be able to lower our list price without impacting our net price," and counseled waiting until early 2020 to reduce prices. Two weeks before this email, Eli Lilly executives had raised the possibility that PBMs would object to a list price reset because it would: (a)

result in a reduction in administrative fees for PBMs, (b) reduce rebates, which would impact PBMs' ability to satisfy rebate guarantees with some clients, and (c) impair their clients' ability to lower premiums for patients, thereby impacting their market competitiveness. An excerpt of this email is shown below:

Figure 17: Eli Lilly internal email re potential price reductions



Message

From: Terrence M Lyons [redacted]
Sent: 6/14/2018 2:56:33 PM
To: Enrique A Conterno [redacted]
CC: Frank D Cunningham [redacted] Michael B Mason [redacted]; Joshua L Smiley [redacted]
Subject: Reply: Tomorrow

Enrique:

I anticipate that the PBMs may raise the following objections and/or considerations in connection with a contemplated list price reset:

(1) Reduction in the absolute amount of Admin Fees earned upon insulin claims/utilization (since this is expressed as a percentage) while still performing comparable/identical services governed by the Admin Fee;
(2) Reduction in absolute rebate amounts pressuring the PBMs ability to satisfy contractually obligated rebate guarantees with some clients (employers and insurance plans) in the near/intermediate term;
(3) Inability to modify/resubmit premiums and associated formularies for Part D plans for the 2018 (and perhaps 2019) plan year(s), or risk that such adjustments may impair market competitiveness (i.e rebate levels on lower gross price levels translating to higher plan premiums).

TML

Terrence M. Lyons
Vice President Finance | CFO Lilly Diabetes
[redacted]

316. Insulin price increases were driven, in part, by tactics the PBMs employed in the early 2010s. At that time, the PBMs began to aggressively pit manufacturers against each other by implementing formulary exclusions in the insulin therapeutic class, which effectively stopped the Manufacturers from reaching large blocks of patients. This tactic boosted the size of rebates and catalyzed the upward march of WAC prices. The Manufacturers responded to these formulary

exclusion threats by raising WAC prices aggressively—increases that often were closely timed with price changes by competitors.

317. The internal memoranda and correspondence show that PBM formulary exclusion lists have contributed to higher rebates in the insulin therapeutic class. Manufacturers have increased rebates to respond to formulary exclusion threats, in order to preserve revenue and market share through patient access. There also is clear evidence that increases in rebates are associated with increased list prices, such that the PBM Defendants' demands for increased rebates directly contributed to rising insulin prices. As Eli Lilly's CEO, David Ricks, has explained, Eli Lilly agreed to raise list prices to fund higher rebates and fees for the PBMs:

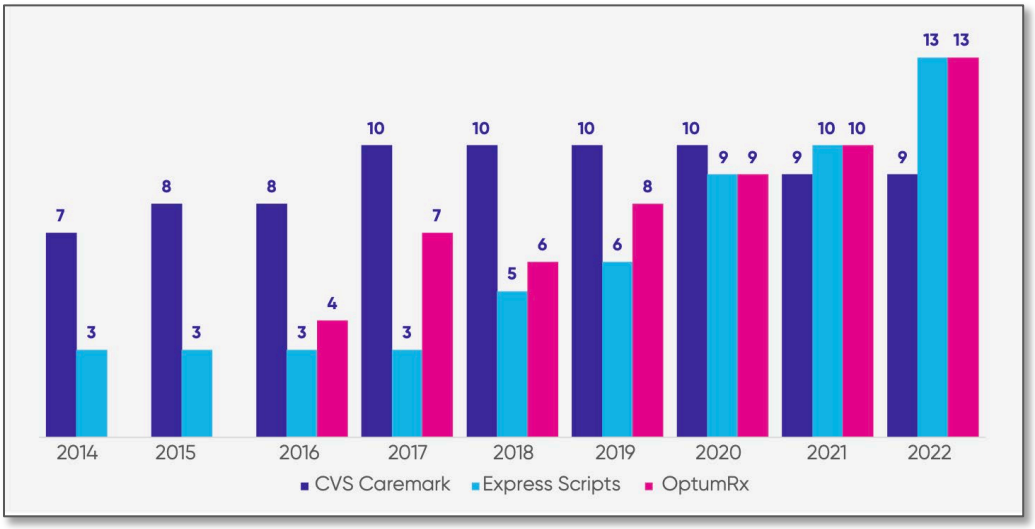
> Getting on [a] formulary is the best way to ensure most people can access our medicines affordably—once again, that's how insurance is supposed to work. But that requires manufacturers to pay ever-increasing rebates and fees, which can place upward pressure on medicines' list prices. If we cannot offer competitive rebates, our medicines may be excluded from formularies, and people cannot access them. Last year alone, to ensure our medicines were covered, Lilly paid more than $12 billion in rebates for all our medicines, and $1 billion in fees. Last year, about eighty cents of every dollar spent on our insulins went to pay rebates and fees.

318. Insulin was among the first classes of drugs to face PBM formulary exclusions, and the number of insulins excluded has increased over time.[69] In 2014,

[69] Xcenda, *Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access* (May 2022), available at www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.

Express Scripts and CVS Caremark excluded 6 and 7 insulins, respectively. OptumRx excluded 4 insulins in 2016, its first year with an exclusion list. As of 2022, insulins have faced 193 total plan-years of exclusion across the PBMs since 2014:

Figure 18: Insulin exclusions by plan-year



319. There also is clear evidence the insulin manufacturers have made price increase decisions due to countervailing pressures in their relationships with PBMs. Higher list price increases the dollar value of rebates, discounts, and other fees that a manufacturer can offer to a PBM, all of which are based on a percentage of the list price. Internal documents show that insulin manufacturers were sensitive not only to their own bottom lines, but to the bottom line of PBMs that set formularies, without which a manufacturer's product would likely lose significant market share.

320. Exclusions, driven in part by perverse PBM incentives, have had an extensive impact on patients' access to insulin. Lower list-priced insulins have been available since 2016—including follow-on insulins[70] (Admelog, Basaglar, Lyumjev, Fiasp), "authorized generic" insulins (Lispro, Insulin Aspart),[71] and, more recently, biosimilar insulins. However, PBMs often exclude these insulins from their formularies in favor of products with higher list prices and larger rebates. For example, two of the three PBM Defendants have included the two insulin authorized generics on their formulary exclusion lists since 2020, instead favoring the higher

[70] The term "follow-on biologic" is a broad, overarching term. The designation of "biosimilarity" is a regulatory designation. "Follow-on biologics" are copies of originator innovator biologics. Those approved via the Biologics License Application (BLA) regulatory pathway (Public Health Service Act) are referred to as "biosimilars." Those approved via the New Drug Application (NDA) regulatory pathway (Food, Drug, and Cosmetic Act) retain the designation "follow-on" biologics. *See* Richard Dolinar, et al., *A Guide to Follow-on Biologics and Biosimilars with a Focus on Insulin*, 24 Endocrine Practice 195-204 (Feb. 2018), available at https://www.sciencedirect.com/science/article/abs/pii/S1530891X20353982#:~:text=Follow%2Don%20biologics%20are%20copies,regulations%20involving%20biologics%20are%20complex.

[71] An authorized generic medicine is a "brand name drug that is marketed without the brand name on its label." Additionally, "even though it is the same as the brand name product, a company may choose to sell the authorized generic at a lower cost than the brand name drug." *See Food and Drug Administration. FDA listing of authorized generics,* available at *https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs*.

list-priced equivalents. Remarkably, this was true even though the list prices for these authorized generic insulins can be half the list price of the brand.[72]

321. In addition to the exclusions of authorized generic insulins, lower list-priced biosimilar insulins have also faced PBM formulary exclusions. The first biosimilar insulin was launched in 2021. Due to prevailing market dynamics, two identical versions of the product were simultaneously introduced—one with a higher list price and large rebates, and one with a lower list price and limited rebates—giving payors the option of which to cover. All three PBMs excluded the lower list-priced version in 2022, instead choosing to include the identical product with the higher list price.[73]

322. Excluding lower list-priced medicines from formularies can substantially increase out-of-pocket costs for patients in plans using deductibles or coinsurance, where cost-sharing is typically determined based on the medicine's full

[72] Tori Marsh, *Can't access generic Humalog? There's an even cheaper insulin option available*, GoodRx. (Aug. 26, 2019), available at https://www.goodrx.com/blog/admelog-now-cheaper-than-generic-humalog.

[73] Adam Fein, *Five takeaways from the big three PBMs' 2022 formulary exclusions* (Jan. 19, 2022), available at https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html.

list price.[74] This trend of favoring higher list-priced products has dramatically affected patient affordability and access to insulins.

323. The PBM Defendants and the Manufacturers are complicit. There has been little, if any, attempt by PBM Defendants to discourage Manufacturers from increasing the list price of their products. Instead, the PBMs used their size and aggressive negotiating tactics, such as the threat of excluding drugs from formularies, to extract even more generous rebates, discounts, and fees from the Manufacturers, who have increased their insulin list prices in lockstep.

324. PBMs thus had every incentive to encourage Manufacturers to raise list prices, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs retain a large portion of what they negotiate. In fact, the Manufacturers have been dissuaded from decreasing list prices for their products, which would have lowered out-of-pocket costs for patients, due to concerns that PBMs and health plans would react negatively.

325. Because of the Manufacturer and PBM Defendants' collusive price increases, nearly a century after the discovery of insulin, diabetes medications have become unaffordable for many diabetics.

[74] Adam Fein, *Express Scripts vs. CVS Health: five lessons from the 2020 formulary exclusions and some thoughts on patient impact* (Jan. 2020), available at https://www.drugchannels.net/2020/01/express-scripts-vs-cvs-health-five.html.

C. The Pharmaceutical Payment and Supply Chain

326. The prescription drug industry is comprised of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include manufacturers, wholesalers, PBMs, pharmacies, payors, and patients.

327. Given the complexities of the different parties involved in the pharmaceutical industry, pharmaceuticals are distributed in many ways. Generally speaking, branded prescription drugs, such as the at-issue diabetes medications, often are distributed in one of three ways: (a) from manufacturer to wholesaler (distributor), wholesaler to pharmacy, and pharmacy to patient; (b) from manufacturer to mail-order pharmacy to patient; or (c) from manufacturer to mail-order pharmacy, mail-order pharmacy to self-insured payor, and self-insured payor to patient.

328. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity, i.e., different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that each entity in the pharmaceutical chain pays for a drug is necessarily tied to the price set by the manufacturer.

329. The pricing chain includes self-insured payors like Plaintiff paying PBMs directly. Defendants Express Scripts, OptumRx, and CVS Caremark routinely invoiced Plaintiff for the at-issue diabetes medications.

330. But there is no transparency in this pricing system. Typically, there are two kinds of published prices. One is the Wholesale Acquisition Cost (WAC), which is a manufacturer's price for the drug to wholesalers (and excludes any discounts, rebates, or price reductions). The other is Average Wholesale Price (AWP), which is the price wholesalers charge retailers for a drug. Both WAC and AWP, depending on the context, are sometimes colloquially referred to as "list price."[75]

331. AWP is usually calculated by applying a significant mark-up (such as 20%) to the manufacturer's WAC. AWP does not account for discounts available to various payers, nor is it based on actual sales transactions.

332. Publishing compendiums, such as First DataBank, report both the WAC and the AWP.

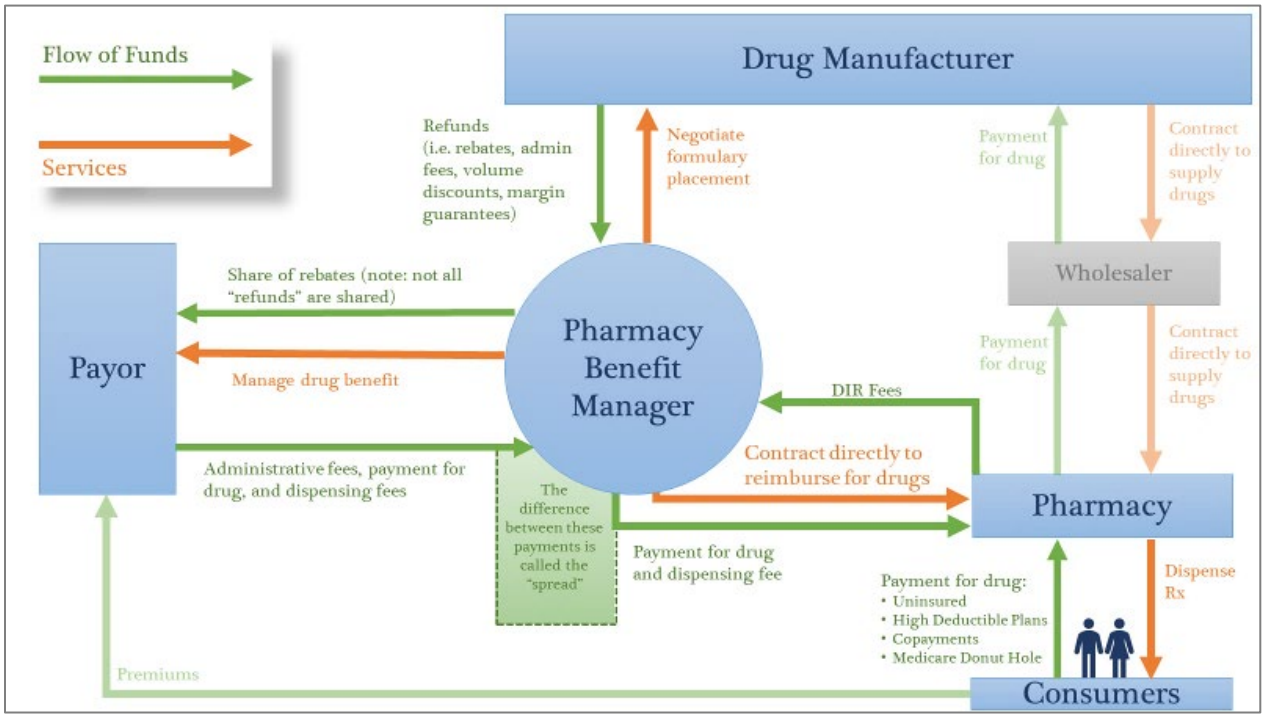
333. As a direct result of the PBMs' conduct, AWP persists as the most commonly and continuously used benchmark price in negotiating reimbursement and payment calculations for both payors and patients.

[75] In general, when this Complaint discusses Defendants' conspiracy to inflate "list prices," Plaintiff is referring to WAC. Because AWP is based on WAC, when a manufacturer raises its WAC, that necessarily results in an increase to the AWP.

D. The PBMs' Role in the Pharmaceutical Payment Chain

334. The PBMs are at the center of the convoluted pharmaceutical payment chain, as illustrated in Figure 19 below.

Figure 19: Insulin distribution and payment chain



335. PBMs (including the PBM Defendants) develop drug formularies, process claims, create a network of retail pharmacies, set the prices in coordination with the Manufacturers that the payor will pay for prescription drugs, and are paid by the payor to reimburse pharmacies for the drugs utilized by the payor's plan participants.

336. The PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and pay fees back to the PBMs. The PBMs reimburse pharmacies for the drugs dispensed.

337. The PBM Defendants also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at-issue here, and directly supply those drugs to patients by mail.

338. Often—including for the at-issue drugs—the PBM Defendants purchase drugs directly from the Manufacturers and distribute them directly to the patients.

339. Even where PBM Defendants' mail-order pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the manufacturers.

340. In addition, and of particular significance here, the PBM Defendants contract with drug manufacturers, including the Manufacturer Defendants. The PBMs extract from the Manufacturers rebates, fees, and other consideration that are paid back to the PBM, including the Manufacturer Payments related to the at-issue drugs.

341. Manufacturers also interact with the PBMs related to other services outside the scope of the Insulin Pricing Scheme, such as health and educational programs, and patient and prescriber outreach with respect to drugs not at-issue in this Complaint.

342. These relationships place PBMs at the center of the flow of pharmaceutical money and allow them to exert tremendous influence over what drugs are available nationwide, on what terms, and at what prices.

343. Historically and today, the PBM Defendants:

a. negotiate the price that payors pay for prescription drugs (based on prices generated by the Insulin Pricing Scheme);

b. separately negotiate a different (and often lower) price that pharmacies in their networks receive for the same drug;

c. set the amount in fees that the pharmacy pays back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme);

d. set the price paid for each drug sold through their mail-order pharmacies (based on prices generated by the Insulin Pricing Scheme); and

e. negotiate the amount that the Manufacturers pay back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme).

344. Yet, for the majority of these transactions, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the same drugs. This absence of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

345. In every interaction that the PBMs have within the pharmaceutical pricing chain, they stand to profit from the prices generated by the Insulin Pricing Scheme.

1. The Rise of the PBMs in the Pharmaceutical Supply Chain

346. At first, in the 1960s, PBMs functioned largely as claims processors. Over time, however, they have taken an ever-expanding role as participants in pharmaceutical pricing and distribution chains.

347. One key role PBMs took on, as discussed above, was negotiating with drug manufacturers—ostensibly on behalf of payors. In doing so, PBMs affirmatively represented that they were using their leverage to drive down drug prices.

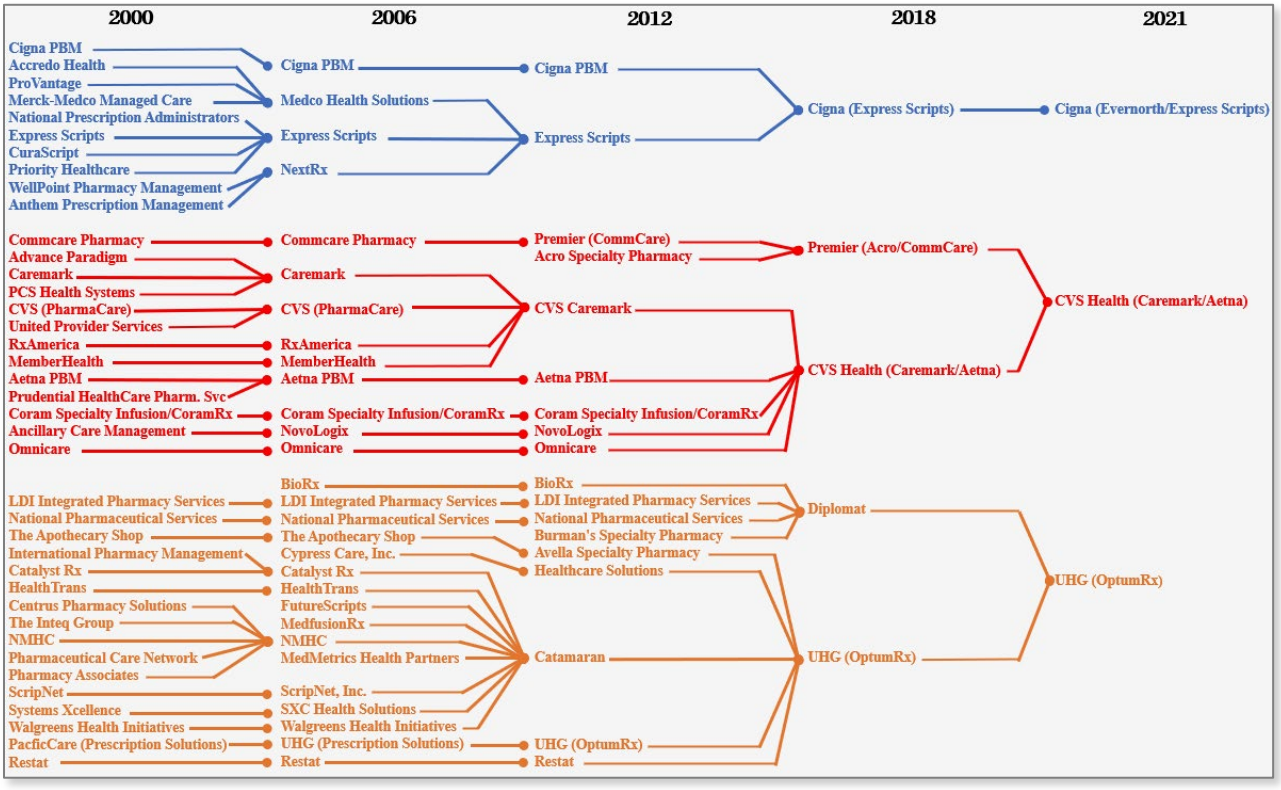
348. In the early 2000s, PBMs started buying pharmacies, thereby creating an additional incentive to collude with manufacturers to keep certain prices high.

349. These perverse incentives still exist today with respect to both retail and mail-order pharmacies housed within the PBMs' corporate families. Further recent consolidation in the industry has given PBMs disproportionate market power.

350. Nearly 40 PBM entities combined into what are now the PBM Defendants, each of which now is affiliated with another significant player in the pharmaceutical chain, e.g., Express Scripts merged with Cigna; CVS bought Caremark (and now also owns Aetna); and UnitedHealth Group acquired OptumRx.

351. Figure 20 depicts this consolidation within the PBM market.

Figure 20: PBM consolidation



352. After merging with or acquiring all of their competitors, and now backed by multi-billion-dollar corporations, the PBM Defendants have taken over the market in the past decade, controlling more than 80% of drug benefits for more than 270 million Americans.

353. Together, the PBM Defendants report more than $300 billion in annual revenue.

354. The PBMs use this market consolidation and the resulting purchasing power as leverage when negotiating with other entities in the pharmaceutical pricing chain.

2. The Insular Nature of the Pharmaceutical Industry

355. The insular nature of the pharmaceutical industry has provided Defendants with ample opportunity for contact and communication with their competitors, as well as with the other PBM and Manufacturer Defendants, so as to plan, agree, and carry out the Insulin Pricing Scheme.

356. For example, each Manufacturer Defendant is a member of the industry-funded Pharmaceutical Research and Manufacturers of America ("PhRMA") and has routinely communicated through PhRMA meetings and platforms in furtherance of the Insulin Pricing Scheme. According to PhRMA's 2019 IRS Form 990, it received more than $515 million in "membership dues." All members are pharmaceutical companies.[76]

357. David Ricks (Chair and CEO of Eli Lilly), Paul Hudson (CEO of Sanofi), and Douglas Langa (President of Novo Nordisk and EVP of North American

[76] PhRMA 2019 Form 990, https://projects.propublica.org/nonprofits/ organizations/ 530241211/202043189349300519/full; PhRMA, *About PhRMA*, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/About-PhRMA2.pdf (last visited Jan. 4, 2023).

Operations), serve on the PhRMA Board of Directors and/or part of the PhRMA executive leadership team.

358. The PBM Defendants also routinely communicate through direct interaction with their competitors and the Manufacturers at trade associations and industry conferences.

359. Each year during the relevant period, the main PBM trade association, the industry-funded Pharmaceutical Care Management Association ("PCMA"), held several yearly conferences, including its Annual Meeting and its Business Forum conferences.[77]

360. The PCMA is governed by PBM executives. As of July 2023, the board of the PCMA included Adam Kautzner (President of Express Scripts), Heather Cianfrocco (CEO of OptumRx), and David Joyner (Executive Vice President and President of Pharmacy Services at CVS Health).

361. As of January 2023, the Board of the PCMA included Alan Lotvin (Executive Vice President of CVS Health and President of CVS Caremark); Amy Bricker (then-President of Express Scripts; now with CVS); and Heather Cianfrocco (CEO of OptumRx). As of March 2023, the PCMA board includes PBM-affiliated

[77] The PCMA's industry funding in the form of "membership dues" is set out in its 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/383676760/202042969349301134/full (last visited Jan. 4, 2023).

members Adam Kautzner (President of Express Scripts); David Joyner (EVP at CVS Health) and Heather Cianfrocco (CEO of OptumRx).

362. All PBM Defendants are members of the PCMA and, due to their leadership positions, wield substantial control over it.

363. Additionally, the Manufacturer Defendants are affiliate members of the PCMA.

364. Every year, high-level representatives and corporate officers from both the PBM and Manufacturer Defendants attend these conferences to meet in person and engage in discussions, including those in furtherance of the Insulin Pricing Scheme.

365. In fact, for at least the last eight years, all Manufacturer Defendants have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PBM conferences.

366. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, Manufacturer Defendants each hosted "private meeting rooms" that offer "excellent opportunities for . . . one-on-one interactions between PBM and pharma executives."[78]

[78] PCMA, *The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21, https://www.pcmanet.org/events/past-*

367. Representatives from each Manufacturer Defendant have routinely met privately with representatives from each PBM Defendant during the Annual Meetings and Business Forum conferences that the PCMA holds (and the manufacturers sponsor) each year.

368. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "an invitation-only LinkedIn Group and online networking community."[79]

369. As PCMA members, the PBM and Manufacturer Defendants clearly utilized both PCMA-Connect, as well as the private meetings at the PCMA conferences, to exchange information and to reach agreements in furtherance of the Insulin Pricing Scheme.

370. Key at-issue lockstep price increases occurred immediately after Defendants had convened at PCMA meetings. For example, on September 26 and 27, 2017, the PCMA held its annual meeting, at which each of the Manufacturer Defendants hosted private rooms and executives from each Defendant engaged in several meetings throughout the conference. On October 1, 2017, just days after the

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events/pcma-annual-meeting-2021/ (an event "tailored specifically for senior executives from PBMs and their affiliated business partners" with "private reception rooms" and "interactions between PBM members, drug manufacturers, and other industry partners") (last visited July 3, 2023).

[79] PCMA, *PCMA-Connect*, https://www.pcmanet.org/contact/pcma-connect/ (last visited July 3, 2023).

conference, Sanofi increased Lantus's list price by 3% and Toujeo's list by 5.4%. Novo Nordisk recommended that their company make a 4% list price increase effective on January 1, 2018, to match the Sanofi increase.

371. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir a matter of hours after Sanofi made its list price increase on Lantus. These price hikes occurred only just weeks after the 2014 PCMA spring conference in Washington, D.C., attended by representatives of all three PBM Defendants.

372. The PBMs control the PCMA and have weaponized it to further their interests and to conceal the Insulin Pricing Scheme. The PCMA has instituted numerous lawsuits and lobbying campaigns aimed at blocking drug pricing transparency efforts, including recently suing the Department of Health and Human Services (HHS) to block the finalized HHS "rebate rule," which would eliminate anti-kickback safe harbors for Manufacturer Payments and instead offer them as direct-to-consumer discounts.

373. Notably, the PCMA's 2019, 2020, and 2021 tax returns report annual revenue for "litigation support" totaling $1.01 million, $2.19 million, and $2.92 million respectively. Prior tax returns available at ProPublica similarly reveal millions of dollars in revenue for "litigation support" (and tens of millions in revenue for "industry relations") year after year.[80]

[80] *See, e.g.*, PCMA 2019-2021 Form 990s and prior years' returns on ProPublica.

374. In addition, communications among the PBM Defendants are facilitated by the fluidity and frequency with which executives move from one PBM Defendant to another. For example:

a. Mark Thierer worked as an executive at Caremark Rx (now CVS Caremark) prior to becoming the CEO of OptumRx in 2016 (and also served as Chairman of the Board for PCMA starting in 2012);

b. CVS Health's current President and CEO Karen Lynch held an executive position at Cigna;

c. Amar Desai served as President for Health Care Delivery at CVS Health before joining Optum Health, where he now serves as CEO.

d. Trip Hofer served in leadership at CVS Health before becoming CEO of Behavioral Health for Optum Health.

e. Bill Wolfe was the President of the PBM Catalyst Rx (now OptumRx) prior to becoming the President of Aetna Rx in 2015 (and also served as a PCMA board member from 2015-2017 while with Aetna Rx);

f. Derica Rice former EVP for CVS Health and President of CVS Caremark previously served as EVP and CFO for Eli Lilly;

g. Duane Barnes was the Vice President of Medco (now Express Scripts) before becoming division President of Aetna Rx in 2006 (and also served as a PCMA board member);

h. Everett Neville was the division President of Aetna Rx before becoming Senior Vice President of Express Scripts;

i. Albert Thigpen was a Senior Vice President at CVS Caremark for 11 years before becoming a Senior Vice President at OptumRx in 2011;

j. Harry Travis was the Chief Operating Officer at Medco (now Express Scripts) before becoming a Vice President at Aetna Rx in 2008; he also served as SVP Member Services Operations for CVS Caremark from 2020-2022; and

k. Bill Kiefer was a Vice President of Express Scripts for 14 years before becoming Senior Vice President of Strategy at OptumRx in 2013.

E. The Insulin Pricing Scheme

375. The market for the at-issue diabetes medications is unique in that it is highly concentrated with no true generics and few biosimilar options. The drugs and biosimilars have similar efficacy and risk profiles.

376. This affords the PBMs significant leverage that, in theory, could be used to negotiate with the Manufacturer Defendants to drive down list prices for the at-issue drugs through open competition.

377. But the PBMs do not want the prices for diabetes medications to decrease. A 2022 report by the Community Oncology Alliance put it this way:

> Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs

> extract in exchange for placing the manufacturer's product drug on a plan sponsor's formulary or encouraging utilization of the manufacturer's drugs.... [T]he growing number and scale of rebates is the primary fuel of today's high drug prices. The truth is that PBMs have a vested interest to have drug prices remain high, and to extract rebates off of these higher prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.[81]

378. The Manufacturer Defendants understand that PBM Defendants make more money as prices increase. This is confirmed by the Senate Insulin Report after committee review of internal documents produced by the Manufacturer Defendants:

> [B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their money on rebates and fees that are based on a percentage of a drug's list price.[82]

379. The documents eventually released by the Senate also show how the Manufacturer Defendants' pricing strategy focuses on the PBMs' profitability. In an internal August 6, 2015, email, Novo Nordisk executives debated delaying increasing the price of an at-issue drug to make the increase more profitable for CVS Caremark, stating:

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[81] Community Oncology Alliance & Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers* (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (last visited Jan. 14, 2023).

[82] Senate Insulin Report at 89.

> Should we take 8/18 [for a price increase], as agreed to by our [pricing committee], or do we recommend pushing back due to the recent CVS concerns on how we take price? . . . We know CVS has stated their disappointment with our price increase strategy (ie taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase . . . it has been costing CVS a good amount of money.[83]

380. The Manufacturer Defendants also understand that because of the PBMs' market dominance, most payors accept the baseline national formularies offered by the PBMs with respect to the at-issue drugs.

381. The Insulin Pricing Scheme was borne from these understandings. Both sets of Defendants realized that if the Manufacturers artificially inflate their list prices to facilitate large, undisclosed Manufacturer Payments back to the PBMs, both the PBMs and Manufacturers would generate billions of unearned dollars. The plan worked.

382. Over the past several years the Manufacturers have raised prices in unison and have paid correspondingly larger Manufacturer Payments to the PBMs.

383. In exchange for the Manufacturers artificially inflating their prices and paying the PBMs substantial amounts in Manufacturer Payments, the PBM Defendants grant the Manufacturer Defendants' diabetes medications elevated prices

[83] Letter from Raphael A. Prober, Counsel for Novo Nordisk Inc., to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Novo_Redacted.pdf (last visited July 3, 2023).

and preferred status on their national formularies. During the relevant period, the rebate amounts (as a proportion of the list price) grew year-over-year while list prices themselves increased.

384. For example, in July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's commercial formulary. Five years later, in 2018, Sanofi rebates were as high as 56% for preferred placement. In 2015, Sanofi offered OptumRx rebates up to 42% for Lantus for preferred formulary placement. That figure grew to 79.75% by 2019. Similarly, in 2014, Novo Nordisk offered Express Scripts 25% rebates for Levemir. That figure climbed to 47% in 2017.

385. Beyond increased rebate demands, the PBM Defendants also have sought and received larger and larger administrative fees from the Manufacturers during the relevant period.

386. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the Manufacturers tripled, reaching more than $16 billion. The study observed that although rebates were sent to payors during this period, PBMs retained the same volume of rebates in pure dollars, due to the overall growth in rebate volume, as well as increases in administrative fees and spread pricing (charging a client payor more for a drug than the PBM pays the pharmacy).

387. Thus—and contrary to their public representations—the PBM Defendants' negotiations and agreements with the Manufacturer Defendants (and the formularies that result from these agreements) have caused and continue to cause precipitous price increases for the at-issue drugs.

388. As a result of the Insulin Pricing Scheme, every payor, including Plaintiff, that pays for and/or reimburses for the at-issue drugs has been overcharged.

389. Moreover, the PBMs use this false price to misrepresent the amount of "savings" they generate for diabetics, payors, and the healthcare system. For example, in January 2016, Express Scripts' president Tim Wentworth stated at the 34th annual JP Morgan Healthcare Conference that Express Scripts "saved our clients more than $3 billion through the Express Scripts National Preferred Formulary."[84] Likewise, in April 2019, CVS Caremark president Derica Rice stated, "Over the last three years . . . CVS Caremark has helped our clients save more than $141 billion by blunting drug price inflation, prioritizing the use of effective, lower-cost drugs and reducing the member's out-of-pocket spend."[85]

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[84] Surabhi Dangi-Garimella, *PBMs Can Help Bend the Cost Curve: Express Scripts' Tim Wentworth,* AJMC (Jan. 12, 2016), https://www.ajmc.com/view/pbms-can-help-bend-the-cost-curve-express-scripts-tim-wentworth (last visited Jan. 15, 2023).

[85] CVS Health, *CVS Health PBM Solutions Blunted the Impact of Drug Price Inflation*, Helped Reduce Member Cost, and Improved Medication Adherence in 2018 (Apr. 11, 2019), https://www.cvshealth.com/news-and-insights/press-releases/cvs-health-pbm-solutions-blunted-the-impact-of-drug-price (last visited Jan. 11, 2023).

390. In making these representations, the PBMs fail to disclose that the amount of "savings" generated is calculated based on the false list price, which is not paid by any entity in the pharmaceutical pricing chain and which all Defendants are directly responsible for artificially inflating.

391. The Insulin Pricing Scheme is a coordinated effort between the Manufacturer and PBM Defendants in which each agreed to, and did, participate in, and which created enormous profits for Defendants. For example:

a. The Manufacturers and the PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that form and fuel the scheme. As part of these communications, the Manufacturers are directly involved in determining not only where their own diabetes medications are placed on the PBMs' formularies and with what restrictions, but also in determining the same for competing products;

b. The Manufacturers and the PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs' drug utilization tracking efforts and mail-order pharmacy claims, internal medical efficacy studies, and financial data. Defendants then use this information in coordination to set the false prices for the at-issue medications and to

construct their formularies in the manner that is most profitable for both sets of Defendants. The data that is used to further this coordinated scheme is compiled, analyzed, and shared either by departments directly housed within the PBM or by subsidiaries of the PBM, as is the case with OptumRx (which utilizes OptumInsight and Optum Analytics); and

c. The Manufacturers and the PBMs engage in coordinated outreach programs directly to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters in tandem to send out to diabetes patients on behalf of the PBMs' clients. For example, the Grassley-Wyden committee recently released an email in which Eli Lilly discussed paying Defendant UnitedHealth Group and OptumRx additional rebates for every client that was converted to formularies that exclusively preferred Eli Lilly's at-issue drugs, including Humalog. The email continued: "United's leadership committee made one ask of Lilly – that we are highly engaged in the communication/pull through plan.[86] I of course indicated we fully expect

[86] "Pull through" is an industry term that refers to marketing by Manufacturers to physicians, among others, aimed at moving market share and increasing sales for a certain product following the PBM granting that product preferred placement on its formulary.

> to support this massive patient transition [to Eli Lilly's at-issue drugs favored by United] and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation and DBU execution."

392. Rather than using their prodigious bargaining power to lower drug prices as they claim, Defendants used their dominant positions to work together to generate billions of dollars in illicit profits at the expense of payors and diabetics.

F. The Rebate Agreements' Parity Terms Limit Use of Utilization Management Measures

393. The PBMs have historically represented that they work on behalf of their clients to manage the cost of their drug benefits. Their clients in turn have relied on them to design and manage formularies to ensure the safe and cost-effective dispensing of prescription drugs, including the insulin drugs. Toward that end, the PBMs have represented to their clients and the public that they would make formulary decisions and use utilization management ("Utilization Management" or "UM") measures to prefer safe and cost-effective drugs, including insulin drugs. Those representations often were false. In reality, for more than a decade, the PBMs have been working with the Manufacturers toward a common illegitimate purpose to increase the cost of the at-issue drugs.

394. The PBMs and the Manufacturers formed a common purpose to use their relationships and the association between their entities to conduct deceptive

enterprises. While the PBM Defendants have represented they would work for their clients and make formulary decisions and implement Utilization Management measures in their interests to make the insulin drugs more affordable, behind closed doors they entered into confidential agreements with the Manufacturers to block UM measures that would have limited dispensing to medically appropriate uses and controlled costs. In exchange for these lucrative agreements, the PBMs provided the Manufacturers with detailed prescribing data which limited implementation of UM measures that would have aided in controlling the cost of insulin.

395. Tellingly, the agreements with the Manufacturers preserved lockstep parity treatment with their competitors' insulin drugs for preferred access on the PBM Defendants' formularies, requiring that UM measures could be applied only if they were applied to all insulin drugs in the therapeutic class. All of these actions were contrary to the interests of the PBMs' clients and furthered the common purpose between the Manufacturers and PBM Defendants.

396. The PBM Defendants and the Manufacturers regularly discussed and agreed about which, if any, UM measures would be utilized for particular insulin drugs. Had they been implemented, the UM measures would have helped control the cost of the insulin drugs. These measures include days' supply quantity and daily dosage limits, NDC blocks (blocking certain insulin drugs from the formularies), prior authorizations (which require additional PBM approval before drug is

dispensed) and step edits (which require that a patient try a different preferred drug before being given a non-preferred, often cheaper insulin drug).

397. The PBM Defendants maintain internal committees that determine which drugs are placed on their formularies. These committees are comprised of company personnel. Express Scripts refers to this committee as the Value Assessment Committee; OptumRx refers to this committee as the Formulary Management Committee; and CVS Caremark refers to this Committee as the Formulary Review Committee.

398. In addition, the PBM Defendants have trade relations employees who are responsible for negotiating rebate agreements with drug manufacturers. CVS Caremark and Express Scripts refer to this committee as the Trade Relations Group and OptumRx refers to this committee as the Industry Relations Group.

399. Years ago, the PBM Defendants devised and managed what were known as "open" formularies—formularies that offered varying degrees of plan coverage and benefits for virtually all available FDA-approved drugs. Consequently, with open formularies, drug companies sought to have their drugs placed by PBMs on the formulary that allowed the easiest access to their drugs.

400. Subsequently, however, the PBM Defendants began shifting to "closed" formularies as the default choice for their clients.[87] "Closed" formularies provide tiered benefits, and unlike open formularies, they restrict the overall number of drugs that are entitled to receive any plan prescription drug benefit. For example, while clients traditionally had to opt into closed formularies, by 2014, Express Scripts' national formulary was a closed formulary, and clients had to affirmatively opt out of it.[88]

401. The PBMs' control over the formulary design and administration process has meant that, in performing their formulary functions, they were ostensibly acting as either trustees and/or agents for their clients' benefit. While the PBMs have attempted to avoid fiduciary status by inserting into their contracts self-serving conclusory statements concerning their purported "non-fiduciary" status, the provisions in the PBM Defendants' standard, uniform contracts (and the actions of the PBM Defendants), demonstrate multiple circumstances in which the PBMs have exercised discretionary authority over the management of the services provided, authority and control over the administration of drug benefits being offered, and authority and control over the clients' plan assets.

[87] Thomas Reinke, *PBMs Just Say No to Some Drugs — But Not to Others*, Managed Care Mag. (Apr. 5, 2015).
[88] *Id*.

402. Such circumstances include, but are not limited to, the PBMs' authority to manage and control: (a) the applicable formulary/formularies of each health plan; (b) each health plan's (or other client's) contractual rights to a share of manufacturer rebates paid to the PBM Defendants; (c) benefit claims from individual health plan participants; and (d) the selection and retention of the adjudicator of health plan participants' appeals of denied benefit claims.

403. As they have grown and consolidated, the PBM Defendants have increased their control over formulary decisions for the vast majority of patients in the United States. The PBM Defendants now control formulary decisions for some 245 million Americans (often referred to as "covered lives" by the PBMs and by the Manufacturers with whom they contracted).

404. Over at least the last two decades, the Manufacturers have made millions of dollars annually in rebate payments to the PBM Defendants in exchange for access for their insulin products on the PBMs' formularies. Most troubling is that the rebate agreements with the Manufacturers required that the PBMs not implement Utilization Management measures, which would have helped ensure the cost-effective use of insulin drugs across America.

405. The collusive relationships between the Manufacturers and the PBM Defendants facilitated the formation of agreements that corrupted the policing UM mechanisms that the PBM Defendants would otherwise have employed, directly

resulting in the economic and social impact of the high cost of insulin on virtually every community in America. The motivation for the PBMs was the huge profits they pocketed in the form of rebates and other fees they received.

406. The PBMs have insisted they do not negotiate the prices that the Manufacturers charge for the insulin products. OptumRx told the Senate Finance Committee that it "does not set or affect" insulin manufacturers' list prices.[89] Express Scripts told the Committee that "[n]othing in our agreements prohibits any manufacturer from decreasing the wholesale acquisition cost ('WAC'), also referred to as list price, of a drug."[90] For its part, CVS Caremark insisted that "manufacturers are solely responsible for setting, raising, or lowering list prices."[91]

407. However, the PBMs' control over formulary access has a direct correlation to whether the Manufacturers would be forced to compete on price. For example, throughout their negotiations with the Manufacturers, the PBMs have agreed that, in exchange for rebates, the PBMs would not "disadvantage" their insulin

[89] *See* Optum Response to the Senate Finance Committee Question No. 3, available at https://www.finance.senate.gov/imo/media/doc/OptumRx_Redacted.pdf.

[90] Gibson Dunn Letter to Senator Grassley and Senator Wyden (April 16, 2019), at 4, available at https://www.finance.senate.gov/imo/media/doc/Cigna%20(ESI)_Redacted.pdf.

[91] Enu Mainigi letter to Senator Grassley and Senator Wyden (April 26, 2019), available at http://www.finance.senate.gov/imo/media/doc/_FINAL%20PDF%20-%20CVS%20Caremark_Redacted.pdf.

drugs, i.e., would not place Utilization Management restrictions on the use of the Manufacturers' insulin products.

408. The PBM rebate contracts use the term "disadvantaged" any time when a Manufacturer's product is subject to PBM Utilization Management measures—prior authorization, NDC blocks, counter-detailing, co-pay differentials, or a step edit that negatively affects the reimbursement and/or formulary status of the product as compared to others in its designated competitive product category.[92]

409. Effectively, the use of parity terms has meant that the rebate agreements required the lockstep application of PBM Utilization Management measures, conditioning payment of rebates only if these limitations were applied (if at all) to all other drugs in their formulary's competitive drug category.

410. In exchange for increased rebates, the parties agreed that none of the preferred branded insulin drugs would be disadvantaged and that they all would have the same UM restrictions, if any. These parity and disadvantaged contract terms had the intended effect of the PBMs and the Manufacturers sharing a common purpose of ensuring the access to their expensive branded insulins without UM limitations.

411. For example, Express Scripts' rebate agreements with Sanofi stipulated Sanofi would pay no rebates if its drugs were "disadvantaged":

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[92] *See, e.g.*, Fourteenth Amendment to the Rebate Agreement between Caremark PCS Health, LLC and Sanofi-Aventis U.S. LLC (August 1, 2018), CVSCM_SFC_0004331.

> In order for any utilization of Lantus or Toujeo, regardless of NDC, to be eligible for the Rebates . . . each of the following conditions must be met for which ESI claims a Rebate . . . : (i) All Lantus and Toujeo NDCs must be on [the] Preferred brand Formulary tier at the lowest co-pay or co-insurance . . . for brand products with no restrictions on the use of Lantus or Toujeo by Participants, and (ii) all Lantus and Toujeo NDCs must be listed on the preferred brand Formulary tier in equal or better with only one manufacturer's branded product in the [competitive product category]; . . . and (v) *at no time may any of the NDCs listed be disadvantaged versus the other product in the same Formulary tier . . .* .[93]

412. ESI uses "disadvantaged" to the same effect in its Novo Nordisk contract. For example, Victoza rebates for preferred formulary status were conditioned on its being "neither restricted nor *disadvantaged* to any product in the Branded NIAD Therapeutic Class, excluding metformin combination drugs."[94]

413. OptumRx includes the same parity terms in its agreements with Manufacturers. For example, the OptumRx rebate agreement with Sanofi[95] required that, in exchange for "Preferred" status on OptumRx formularies, under the

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[93] Express Scripts, Inc. Eighteenth Amendment to the Preferred Savings Grid Rebate Program Agreement with Sanofi-Aventis (January 1, 2017), available at https://www.finance.senate.gov/imo/media/doc/Cigna%20(ESI)_Redacted.pdf (emphasis added).

[94] Express Scripts, Inc. Amendment to the Preferred Savings Grid Rebate Program Agreement (January 1, 2017), at Cigna-SFC-00009583, available at https://www.finance.senate.gov/imo/media/doc/Cigna%20(ESI)_Redacted.pdf (emphasis added).

[95] *See* Fourteenth Amendment to the Rebate Agreement between OptumRx, Inc. and Sanofi-Aventis U.S. LLC (January 1, 2019), ORX_Sen_Fin_0009384.

"Conditions of Rebate," "in the event that a package form of Lantus is *disadvantaged* to more than one (1) comparable package form, all NDC's of Lantus, i.e. both vial and pen, shall be ineligible for Rebates . . . ."[96]

414. CVS Caremark told the Senate Finance Committee that it "makes no agreement to eliminate prior authorization, step therapies, or other utilization management methods,"[97] but that statement was false. In fact, CVS Caremark uses "disadvantaged" similarly in its contracts with the Manufacturers, in that it agreed not to "discourage the utilization of the Product in favor of a Competitive Product."[98] For example, the CVS Caremark contracts require that for rebates to be payable for Sanofi's insulin drugs, they could not be subject to "(i) NDC blocking, (ii) prior authorization requirements, (iii) quantity limits (iv), counter-detailing or counter-promoting, (v) switching or therapeutic substitution, and (vi) step edits.[99]

415. The same was true for CVS Caremark's contract with Eli Lilly, which stipulated that the payment of rebates for preferred status was conditioned on Eli

[96] ORX Sen_Fin_0009112 (emphasis added).

[97] Enu Mainigi letter to Senator Grassley and Senator Wyden (April 26, 2019), available at https://www.finance.senate.gov/imo/media/doc/_FINAL%20PDF%20-%20CVS%20Caremark_Redacted.pdf.

[98] *See, e.g.*, Fourteenth Amendment to the Rebate Agreement between Caremark PCS Health, LLC and Sanofi-Aventis U.S. LLC (August 1, 2018), CVSCM_SFC_0004352.

[99] *Id.*

Lilly's insulin products not being "subject to *Disadvantaging* in the Competitive Category . . . ."[100]

416. According to the same agreement, "'[d]isadvantaging' means intervention activities focused on specific prescriptions for a Product where such activities are reasonably intended to discourage the utilization of the Product in favor of a Competitive Product. . . . ."[101]

417. The PBM enterprises used these lockstep parity terms to impose limits on the use of UM measures across the entire class of these most expensive branded insulins. The PBMs' rebate agreements conditioned preferred formulary status on the rebate payments on each Manufacturer's drug not being disadvantaged by UM measures unless the entire market basket of competing drugs was treated the same.

418. These parity terms freed the Manufacturers from any need to compete on price, and instead resulted in the lockstep, ever-increasing "shadow pricing" demonstrated herein.

419. As alleged more fully herein, each member of each PBM Enterprise thus conducted and participated in the conduct of their respective enterprises through a

[100] Medicare Part D Program Rebate Agreement between CVS Caremark Part D Services, LL.L.C. and Eli Lilly and Company (January 1, 2018), at CVSCM_SFC_0004833, available at https://www.finance.senate.gov/imo/media/doc/_FINAL%20PDF%20-%20CVS%20Caremark_Redacted.pdf (emphasis added).

[101] *Id.* at CVSCM_SFC_0004836.

pattern of racketeering activity in which they formed a common purpose of growing the Manufacturers' insulin drugs without UM restrictions.

G. Defendants Blocked Access to Cheaper Biosimilar Insulin Products by Imposing "Fail First" Requirements

420. The Manufacturer Defendants' brand drug rebate agreements with the PBMs also delayed or prevented coverage of biosimilar insulins by requiring step therapy, or a "fail-first" requirement. Such a requirement mandates that a patient must fail first on the reference biologic before becoming eligible for the biosimilar.[102] Such requirements were originally intended to control the costs posed by high-dollar therapies.

421. The agreements between the PBMs and the Manufacturers have required an explicit commitment not to cover biosimilar insulins at all or to do so only in the rarest of circumstances—in effect, to make the brand-name insulins the only one available on their formularies. As a direct result of these exclusive dealing contractual commitments, the biosimilar insulins have not been available on the PBMs' formularies at all or are designated reimbursable only in "fail first" cases.[103]

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[102] *See* Letter from the Association for Accessible Medicines and the Biosimilars Counsel to Lina Khan, Chair of the Federal Trade Commission (May 23, 2022), available at https://accessiblemeds.org/sites/default/files/2022-05/FTC-PBM-Business-Practices-05-20-2022_0_0.pdf (last accessed on Aug. 31, 2023).

[103] *Id.*

422. The "fail first" exception is medically inappropriate and illusory in practice. Most patients do not fail on brand name insulin such that a biosimilar insulin becomes an option under this "fail first" requirement. Moreover, even if a patient did fail on the brand name insulin, a physician would turn to a different drug, not to the biosimilar, which has no clinically meaningful differences from the brand-name insulin.[104]

423. For example, the FDA in July 2021 approved the biosimilar Insulin Glargine-yfgn (branded as Semglee), which is manufactured and sold by newcomers to the market—Viatris and Biocon Biologics.[105] Insulin Glargine-yfgn (Semglee) is interchangeable with Defendant Sanofi's Lantus product, and, according to Viatris, its list price is three times less than Lantus. However, as of January 2023, Glargine-yfgn/Semglee does not appear on CVS Caremark's formulary and OptumRx expressly excludes Glargine-yfgn/Semglee (and includes Lantus).

424. Unfortunately, the market for Semglee reflects the perverse incentives by which PBMs prefer brands with a high list price and high rebate over biosimilar insulins with a lower list price.

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[104] *See, e.g.*, *A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets*, House Oversight Committee (December 10, 2021), https://oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf (last accessed Aug. 31, 2023), at 8-9.

[105] As explained in n.6, insulin now is regulated as a biologic rather than a drug. Biosimilars are analogous to generic drugs—approved versions of original products that are virtually identical to, and interchangeable with, the original product.

425. As a result, lower cost, high value biosimilar medicines are frequently not accessible to patients.[106] While it may be appropriate for PBMs to work to negotiate lower prices through the use of their formularies, their preference for highly rebated products has often imposed higher net costs on payors and patients at the pharmacy, and limited patient access to lower cost biosimilar insulins.

426. Even when new biosimilar insulins are launched specifically to benefit patients and the health care system by introducing competition to high-priced drugs, the PBMs remain incentivized to retain revenue through their rebate structure, and thus the savings that these biosimilar entrants should have brought to payors and patients have gone partially or wholly unrealized.

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[106] *See, e.g.*, Joshua Cohen, *Insulin's Out-Of-Pocket Cost Burden To Diabetic Patients Continues To Rise Despite Reduced Net Costs To PBMs*, FORBES (Jan. 5, 2021), https://www.forbes.com/sites/joshuacohen/2021/01/05/insulins-out-of-pocket-cost-burden-to-diabetic-patients- continues-to-rise-despite-reduced-net-costs-to-pbms/; *see also* Transcript of FTC Open Commission Meeting, FED. TRADE COMM'N, at 14-15 (Oct. 21, 2021), https://www.ftc.gov/news-events/events/2021/10/open-commission-meeting-october-21-2021 (public commenter Matthew Dinger describing that he feels "completely beholden" to insulin manufacturers, and that "[he] is a job loss away from financial ruin because the concentration of economic power, when it comes to the price of insulin, lies almost entirely in the hands of three companies."). *See also id*. at 15 (public commenter Anna Squires noting that [m]any diabetics live below the poverty line and are unable to afford basic necessities, let alone $900 a month in medications,]" and that "[l]ife giving prescriptions should not be a for-profit business venture for people who already own three homes.").

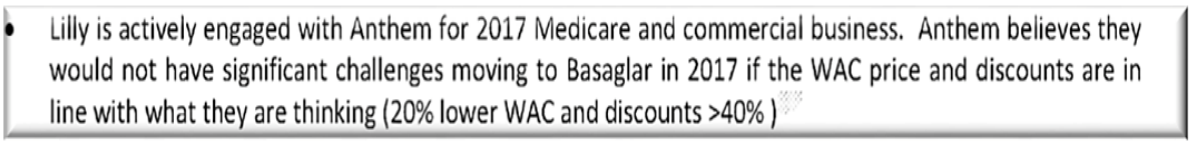
H. The Manufacturers React to Threats of Formulary Exclusion by Raising Rebates Offered to the PBMs

427. Although the PBM Defendants have insisted they had no control over how the Manufacturers price their insulin products, their threats of formulary exclusion illustrate how they used new insulin competitors with lower prices to leverage even higher rebates on the existing insulin drugs.

428. In the face of formulary exclusion threats based on new entrants in the insulin market, the Manufacturers have willingly met the PBM Defendants' demands for increased rebates in order to retain preferred formulary placement and block competitors. For example, in 2016, Sanofi and Novo Nordisk enhanced their rebate offers at the same time Eli Lilly introduced Basaglar, a follow-on biologic to Lantus. Basaglar is a long-acting insulin and is "[c]linically . . . very similar" to Lantus. Because of its near clinical equivalence, Basaglar posed a competitive threat in the long-acting insulin market. PBMs threatened to switch to Basaglar because it was priced lower, and they expected Eli Lilly to offer larger discounts in response.

429. A 2016 Sanofi memo describes the market dynamic whereby a threatened new market entrant would lead not to lower prices, but to greater rebates:

Figure 21: Sanofi memo on introduction of Basaglar



430. In an attempt to avoid PBMs switching to Basaglar, Sanofi and Novo Nordisk increased their rebate bids to respond to Eli Lilly. For example, according to Sanofi internal memoranda, sometime around April 2016, Express Scripts requested bids for its 2017 national commercial formulary and indicated its desire to only add one insulin glargine product to its basal insulin category. Express Scripts communicated to Sanofi that "with the right competitive price, [it] would not have significant challenges moving [from Lantus and Toujeo] to Basaglar" and that Sanofi must enhance its current rebate rate of 42% to maintain current access for their basal insulins.

431. An internal Sanofi memo describes the dynamic where, "at the right competitive price," ESI would not have a challenge moving Basaglar into a preferred position on its formulary:

Figure 22: Sanofi memo on Basaglar pricing

Likely Competitive Approach and Response:

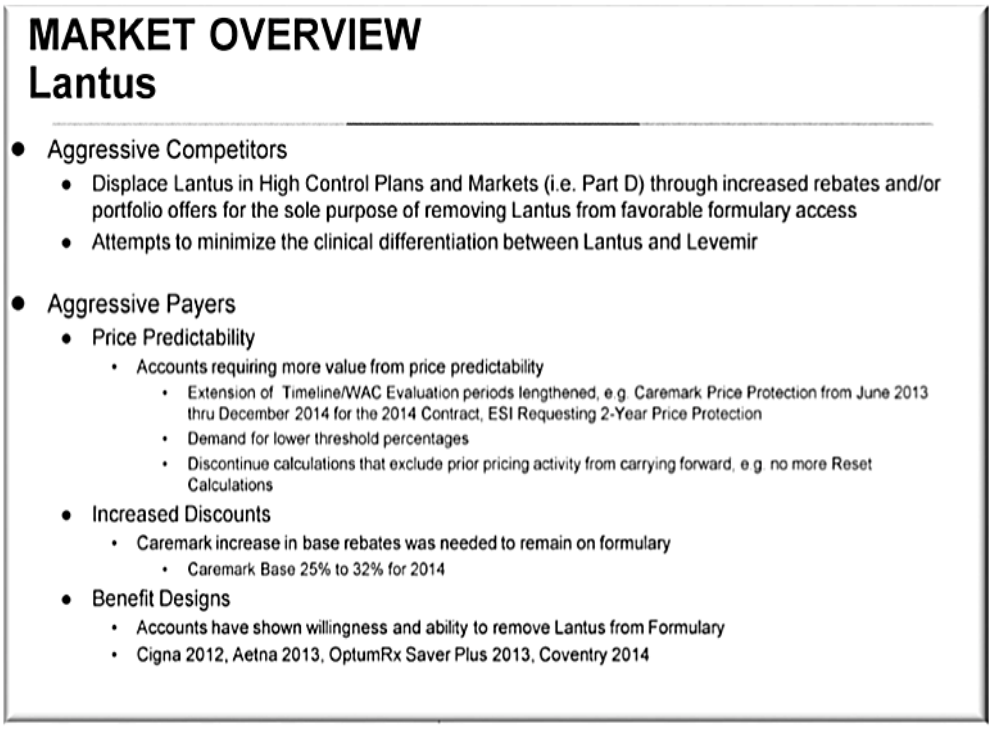
- Lilly is actively engaged with ESI for 2017 commercial business. Pricing has not been confirmed however ESI has informed that the following assumptions pose a threat to Sanofi's glargine franchise:
  - Discounts for Basaglar in the mid 60's have been communicated by ESI to Sanofi. This is likely a starter for ESI to consider excluding Lantus and Toujeo. Modeling assumed 70%.
  - Basaglar WAC will be 15% to 25% less than the WAC price of Lantus. Sanofi modeling assumed 15%.
- ESI has signaled, with the right competitive price, they would not have significant challenges moving to Basaglar in 2017 despite a follow-on biologic (Basaglar) approval.
- In addition ESI has indicated that Novo must also enhance its current rate to maintain current access for their basal insulin(s). Novo is likely to enhance its current rebates given recent Tresiba addition to part D formulary.

432. Rebate contracts confirm that Sanofi increased its offer up to almost 55% off its WAC of $248.51 for Lantus vials and $372.76 for Lantus pens.

433. For the Manufacturers, the mere threat of exclusion pressured them to offer substantially greater rebates to maintain formulary position. This is because formulary exclusions are likely to cause significant loss of a manufacturer's market share, leading to lower revenue. On the other hand, being the exclusive therapy on a formulary has the opposite effect, which incentivizes Manufacturers to offer large discounts to acquire or maintain such status. The use of formulary exclusions has thus led to a market dynamic in which Manufacturers offer ever-higher rebates to avoid exclusion, which has led to higher list prices.

434. For example, before 2013, Sanofi offered an average rebate of 5% on Lantus. However, beginning in 2013, competitors sought to "[d]isplace Lantus in High Control Plans and Markets . . . through increased rebates" to capture market share. In response, Sanofi increased its rebate and discount offerings to remain on their formulary. A Sanofi memo, further explains this dynamic:

Figure 23: Sanofi memo on increased rebates for Lantus



MARKET OVERVIEW
Lantus

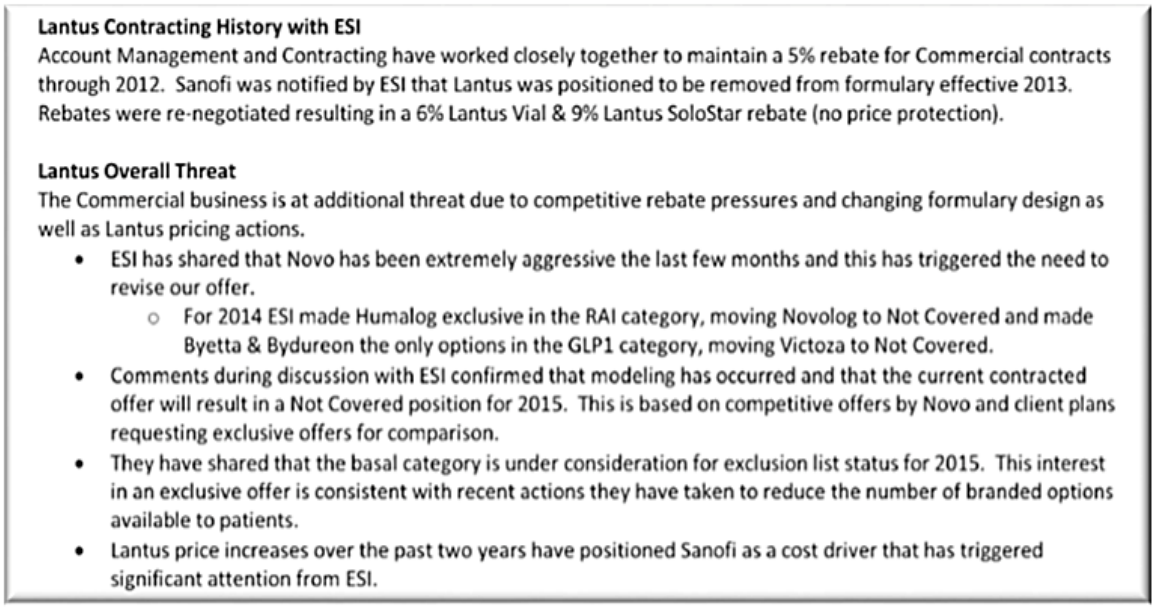
- Aggressive Competitors
  - Displace Lantus in High Control Plans and Markets (i.e. Part D) through increased rebates and/or portfolio offers for the sole purpose of removing Lantus from favorable formulary access
  - Attempts to minimize the clinical differentiation between Lantus and Levemir
- Aggressive Payers
  - Price Predictability
    - Accounts requiring more value from price predictability
      - Extension of Timeline/WAC Evaluation periods lengthened, e.g. Caremark Price Protection from June 2013 thru December 2014 for the 2014 Contract, ESI Requesting 2-Year Price Protection
      - Demand for lower threshold percentages
      - Discontinue calculations that exclude prior pricing activity from carrying forward, e.g. no more Reset Calculations
  - Increased Discounts
    - Caremark increase in base rebates was needed to remain on formulary
      - Caremark Base 25% to 32% for 2014
  - Benefit Designs
    - Accounts have shown willingness and ability to remove Lantus from Formulary
    - Cigna 2012, Aetna 2013, OptumRx Saver Plus 2013, Coventry 2014

435. While the PBM Defendants have touted that utilizing formulary exclusions in the insulin therapeutic class was a way to drive down costs for their clients, internal correspondence and memoranda show that increased use of formulary exclusions did exactly the opposite: WAC (list) prices have continued to increase, leading to higher costs for payors and higher prices for patients at the pharmacy counter.

436. For example, in 2013, when Express Scripts threatened to move patients to other diabetes drugs in order to "break even on [the] rebate line" unless Sanofi increased its Medicare Part D rebate offer for Lantus, Sanofi considered increasing its rebate offer from 7.45% to 15% in order to prevent formulary exclusion. Sanofi

also faced similar pressure to increase rebates for Express Scripts' commercial contracts. Internal Sanofi memoranda show that "Sanofi was notified by [Express Scripts] that Lantus was positioned to be removed from the formulary effective 2013 . . . [and as a result] rebates were re-negotiated." An excerpt from this memo, discussing the threat to Lantus, illustrates that the threats used by ESI to drive up rebates on Sanofi's flagship insulin product Lantus:

Figure 24: Sanofi presentation on formulary threats to Lantus



Lantus Contracting History with ESI

Account Management and Contracting have worked closely together to maintain a 5% rebate for Commercial contracts through 2012. Sanofi was notified by ESI that Lantus was positioned to be removed from formulary effective 2013. Rebates were re-negotiated resulting in a 6% Lantus Vial & 9% Lantus SoloStar rebate (no price protection).

Lantus Overall Threat

The Commercial business is at additional threat due to competitive rebate pressures and changing formulary design as well as Lantus pricing actions.

- ESI has shared that Novo has been extremely aggressive the last few months and this has triggered the need to revise our offer.
  - For 2014 ESI made Humalog exclusive in the RAI category, moving Novolog to Not Covered and made Byetta & Bydureon the only options in the GLP1 category, moving Victoza to Not Covered.
- Comments during discussion with ESI confirmed that modeling has occurred and that the current contracted offer will result in a Not Covered position for 2015. This is based on competitive offers by Novo and client plans requesting exclusive offers for comparison.
- They have shared that the basal category is under consideration for exclusion list status for 2015. This interest in an exclusive offer is consistent with recent actions they have taken to reduce the number of branded options available to patients.
- Lantus price increases over the past two years have positioned Sanofi as a cost driver that has triggered significant attention from ESI.

437. According to internal memoranda, in 2014, Express Scripts and its affiliated businesses managed the prescription drug claims of over 4.6 million people, representing 15% of the total business in the Medicare Part D channel. Rebate agreements confirm Sanofi renegotiated rebates and entered into an agreement to provide up to 10.625% for Lantus, effective January 1, 2014. Rebates

were renegotiated again that same year, and Sanofi increased its rebate offer up to 14.625%, effective October 1, 2014.

438. CVS Caremark and OptumRx used similar formulary exclusion threats to drive up Lantus rebates. Around this same time, other PBMs learned that Sanofi had offered competitive rebates to Express Scripts which caused them to question their rebate status with Lantus. As a result, they too demanded higher rebates and threatened to exclude Lantus from their formulary to achieve this result.

439. For example, in 2014, OptumRx threatened to remove Lantus from its commercial formulary because of Lantus's price increases. Sanofi offered an enhanced rebate for FY2015 in the 15% range, but OptumRx rejected Sanofi's offer and took steps to remove Lantus from its commercial formulary. Sanofi responded with a last-minute bid of a 45% rebate for Tier 2, which OptumRx countered with 45% for Tier 3. According to Sanofi, OptumRx's counteroffer was "ultimately accepted over access concerns to future products and the need to secure access to patient lives."

440. Similarly, in 2016, Express Scripts threatened to remove Lantus and Toujeo from its Medicare Part D formulary and requested that Sanofi submit its "best and final offer" or else face formulary exclusion. According to internal memoranda, during negotiations, Express Scripts told Sanofi that it was justified in removing Lantus and Toujeo from its Medicare Part D formulary because it had allowed "quite

a few years of price increases" and that Novo Nordisk's rebate offer was more competitive. In response to Express Scripts' threat, Sanofi discussed revising its rebate offer up to 40% with 4% price protection for Lantus and Toujeo.

441. Although contracts with PBMs included larger and larger rebates, the Manufacturers still expected to remain profitable—up to a point. For example, on July 28, 2017, one Sanofi official wrote to colleagues after considering their offer to CVS Caremark for placement on the Part D formulary: "After inclusion of additional fees, we are still profitable up to an 89% rebate." The official included an analysis that assumed "CVS would need to shift 68.9% of [its] glargine volume to Novo to break even (at an assumed 81% rebate offer)." In its analysis, Sanofi compared various negotiation scenarios including a "no contract" scenario, which it determined would be more profitable to the company even with the resulting reduction in sales volume and revenue. One of the deciding factors was optics, as one colleague put bluntly, was: "How would it look to be removed from the largest Medicare plan?"

442. As PBMs expanded the practice of using formulary exclusions to extract greater rebates, Sanofi's counterstrategy was to bundle unrelated products that had been excluded—Lantus and an epinephrine injection called Auvi-Q—to win formulary inclusion for both. (Bundling is a practice where manufacturers offer rebates and discounts for multiple products, but only if certain conditions are met.)

443. Sanofi faced significant financial pressure across all accounts, and sought to include bundling agreements in several of its contracts. While negotiating contracts for the 2015/2016 plan year, Express Scripts advised Sanofi that it needed to be far more aggressive with rebate offers to gain access to the PBM's commercial book of business than in past years. Internally, Sanofi officials warned in a memo that "Novo, specifically Levemir, has changed the game with regard to rebates," and that Sanofi would "need to rebate aggressively." A separate presentation describes "[c]ontracts that increase Lantus rebates if Auvi-Q is added to [the] formulary thus creating a bundled arrangement," and notes that the company had even considered a "triple product bundle" with Toujeo, despite concerns about the arrangements triggering Medicaid best price.

444. This counterstrategy was not limited to Sanofi. An internal memo shows that Sanofi's competitors were using the same strategy: "Lantus is losing accounts and share within the institutional channel because of aggressive discounting and bundled contract offerings from Novo Nordisk and Lilly."

445. For example, Novo Nordisk secured contract terms from CVS Caremark's Part D business in 2013 that tied its "exclusive" rebates for insulin to formulary access for its Type 2 diabetes drug Victoza. The exclusive rebates of 57.5% for Novolin, Novolog, and Novolog Mix 70/30 were more than three times higher than the 18% rebate for plans that included two insulin products on their

formulary. In order to qualify for the exclusive rebate, the plans would also need to list Victoza, a GLP-1 agonist, on their formulary, exclude all competing insulin products, and ensure "existing patients using a [c]ompeting [p]roduct may not be grandfathered."

I. Defendants Play Down the Insulin Pricing Scheme and Its Harms

446. On April 10, 2019, the U.S. House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, "Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin."[107]

447. Representatives from all Defendants testified at the hearing and admitted that the price for insulin had increased exponentially over the past 15 years.

448. Further, each Defendant conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:

a. Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, testified: "A lack of meaningful competition allows the [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs."

[107] Transcripts available at https://www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3 (last visited July 3, 2023) (hereinafter *Priced Out of a Lifesaving Drug*).

b. Thomas Moriarty, General Counsel for CVS admitted, "A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, prices for insulin have increased nearly 50 percent. Over the last ten years, [list] price of one product, Lantus, rose by 184 percent."

c. Mike Mason, Senior Vice President of Eli Lilly, testified when discussing how much diabetics pay out-of-pocket for insulin: "it's difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don't have affordable access to chronic medications."

d. Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified: "Patients are rightfully angry about rising out-of-pocket costs for many medicines and we all have a responsibility to address a system that is clearly failing too many people . . . we recognize the need to address the very real challenges of affordability . . . . [s]ince 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients."

e. Doug Langa, Executive Vice President of Novo Nordisk, testified: "On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list]

> price matters to many, particularly those in high-deductible health plans and those that are uninsured."

449. None of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.

450. Instead, the written testimony of Novo Nordisk President Doug Langa's recognized "misaligned incentives" that have led to higher drug costs, including for insulin: "Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others." Likewise, Mr. Langa's responses to questions for the record conceded that "[t]he disadvantage of a system in which administrative fees are paid as a percentage of the list price is that there is increased pressure to keep list prices high. . . ." The hearing transcript records Mr. Langa's further comments in this regard:

> So as you heard from Dr. Cefalu last week of the ADA [American Diabetes Association], there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high. And *we've*

> *been participating in that system* because the higher the list price, the higher the rebate . . . There is a significant demand for rebates…. *We're spending almost $18 billion a year in rebates*, discount, and fees, *and we have people with insurance with diabetes that don't get the benefit of that*. (emphasis added)

451. Eli Lilly admitted that it raises list prices as a quid pro quo for formulary positions. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly, testified:

> Seventy-five percent of our list price is paid for rebates and discounts . . . . $210 of a vial of Humalog is paid for discounts and rebates. . . . We have to provide rebates [to PBMs] in order to provide and compete for that [formulary position] so that people can use our insulin.

In the very next question, Mr. Langa of Novo Nordisk was asked, "[H]ave you ever lowered a list price? His answer, "We have not."

452. Sanofi's Executive Vice President for External Affairs, Kathleen Tregoning, similarly testified:

> The rebates is [sic] how the system has evolved. . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Her written response to questions for the record acknowledged that "it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product."

453. The PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher Manufacturer Payments paid by the Manufacturer Defendants.

454. In her responses to questions for the record, Amy Bricker—former President of Express Scripts and a former PCMA board member—confirmed that "manufacturers lowering their list prices" would give patients "greater access to medications." Yet when asked to explain why Express Scripts did not grant an insulin with a lower list price preferred formulary status, she answered, "Manufacturers do give higher discounts [i.e., payments] for exclusive [formulary] position . . ." When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated plainly, "We'll receive less discount in the event we do that."[108]

455. As Dr. Dutta, Senior Vice President of OptumRx, reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because "it would cost the payer more money to do that . . . [b]ecause the list price is not what

[108] Buried in Express Scripts' 2017 10-K is the following: "We maintain contractual relationships with numerous pharmaceutical manufacturers, which provide us with, among other things administrative fees for managing rebate programs, including the development and maintenance of formularies that include particular manufacturer's products . . . ." That is, the Manufacturers pay the PBMs to effectively participate in the creation of formularies that payors are required to adopt as a condition for obtaining PBM services. Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017) at 24. It also notes that its business would be "adversely affected" if it were to "lose [its] relationship with one or more key pharmaceutical manufacturers." *Id.*

the payer is paying. They are paying the net price."[109] In other words, under the Insulin Pricing Scheme, PBMs and manufacturers can make a drug with a lower list price effectively more expensive for payors and then ostensibly save payors from that artificially-inflated price by giving preference to drugs that had higher list prices to begin with (yielding higher Manufacturer Payments to the PBMs).

456. On May 10, 2023, the U.S. Senate Committee on Health, Education, Labor, and Pensions held a hearing titled, "The Need to Make Insulin Affordable for All Americans." At this hearing, the CEOs and presidents of the Manufacturer and PBM Defendants doubled down on their testimony from 2019. David Ricks, for example, the Chair and CEO of Eli Lilly, testified that his company raised list prices and agreed to pay ever-increasing rebates to secure formulary placement:

> Getting on formulary is the best way to ensure most people can access our medicines affordably . . . . But that requires manufacturers to pay ever-increasing rebates and fees, which can place upward pressure on medicines' list prices. . . . Last year alone, to ensure our medicines were covered, Lilly paid more than $12 billion in rebates for all our medicines, and $1 billion in fees.

457. Paul Hudson, the CEO of Sanofi, likewise indicated that PBMs prefer drugs with higher list prices and that the manufacturers have responded accordingly. In discussing a drug Sanofi introduced with a lower list price, Hudson explained: "It just didn't get listed in any way. If price is really the motivator, it would have been

[109] *Priced Out of a Lifesaving Drug* at lines 1394-95. As noted in the hearing, even the "cheaper" alternative Admelog "costs over $200 a bottle." *Id.* at lines 3121-26.

listed."

458. While all Defendants acknowledged before Congress their participation in conduct integral to the Insulin Pricing Scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like Plaintiff, and its Plan Participants, were unwittingly suffering. Instead, to obscure the true reason for precipitous price increases, each Defendant group pointed the finger at the other as the more responsible party.

459. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the Manufacturer Payments that the PBMs receive are not correlated to rising insulin prices.

460. This testimony is false. The amount the Manufacturers kick back to the PBM Defendants *is directly correlated* to an increase in list prices. On average, a $1 increase in Manufacturer Payments is associated with a $1.17 increase in list price.[110]

461. Thus, reducing or eliminating Manufacturer Payments would lower prices and reduce out-of-pocket expenditures.

462. Further, in large part because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown substantially

[110] https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/ (last visited July 3, 2023).

over the same period that insulin prices have steadily increased. For example, since 2003 Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription.[111]

463. Novo Nordisk's President Doug Langa submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list price] is a significant component" of "what patients ultimately pay at the pharmacy counter." Yet, the Manufacturers urged upon Congress the fiction that the PBMs were solely to blame for insulin prices because of their demands for rebates in exchange for formulary placement. The Manufacturers claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited from rising insulin prices.

464. Given the Manufacturers' claims that rebates were the sole reason for rising prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk, and Sanofi all said only that they would "consider it."

465. In addition, a 2020 study from the Institute of New Economic Thinking titled, "Profits, Innovation and Financialization in the Insulin Industry," demonstrates that during the time insulin price increases were at their steepest,

[111] David Balto, *How PBMs Make the Drug Price Problem Worse,* Hill (Aug. 31, 2016, 5:51 PM), https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse (last visited July 3, 2023).

distributions to the Manufacturers' shareholders in the form of cash dividends and share repurchases totaled $122 billion. In fact, during this time, the Manufacturers spent a significantly lower proportion of profits on R&D compared to shareholder payouts. The paper also notes that "[t]he mean price paid by patients for insulin in the United States almost tripled between 2002 and 2013" and that "per-person spending on insulin by patients and insurance plans in the United States doubled between 2012 and 2016, despite only a marginal increase in insulin use."[112]

466. The 2022 Community Oncology Alliance report found:[113]

> [T]here are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients. . . . PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees, *bona fide* service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor. These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors. . . . The total drug spend of a plan sponsor, regardless of whether it is a federal or state governmental program or a self-funded employer, will inevitably increase because PBMs are incentivized to favor expensive drugs that yield high rebates. . . .

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[112] Rosie Collington, *Profits, Innovation and Financialization in the Insulin Industry*, Inst. For New Econ. Thinking (Apr. 2020), https://www.ineteconomics.org/research/research-papers/profits-innovation-and-financialization-in-the-insulin-industry (last visited July 3, 2023).

[113] Community Oncology Alliance, *supra* note 67.

467. In January 2021, the Senate Finance Report detailed Congress's findings after reviewing more than 100,000 pages of internal company documents from Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts, OptumRx, and Cigna. The report concluded, among other things:

a. The Manufacturer Defendants retain more revenue from insulin than they did in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from $1.5 billion in 2007 to $3 billion in 2018;

b. The Manufacturer Defendants have aggressively raised the list price of their insulin products absent significant advances in the efficacy of the drugs; and

c. The Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Eli Lilly spent $395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014-2018 during which time the company generated $22.4 billion in revenue on these drugs.

468. The truth is that, despite their finger-pointing in front of Congress, the Manufacturers and PBMs are both responsible for their concerted efforts in creating and effectuating the Insulin Pricing Scheme.

J. All Defendants Profit from the Insulin Pricing Scheme

469. The Insulin Pricing Scheme affords the Manufacturer Defendants the ability to pay the PBM Defendants secret but significant Manufacturer Payments in exchange for formulary placement, which garners the Manufacturer Defendants greater revenues from sales without decreasing their profit margins. During the relevant period, the PBM Defendants granted national formulary position to each at-issue drug in exchange for large Manufacturer Payments and inflated prices.

470. The Manufacturer Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated list price.

471. Because of the increased list prices, and related Manufacturer Payments, the PBMs' profit per prescription has grown exponentially during the relevant period as well. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased more than 150% from 2014 to 2018. In fact, for transactions in which the PBM Defendants control the PBM and the pharmacy (e.g., Caremark-CVS pharmacy), these Defendants were capturing an astonishing 40% of the money spent on each insulin prescription (up from only 25% just four years

earlier), even though they do not contribute to the development, manufacture, innovation, or production of the product.[114]

472. The PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in several ways, including: (a) retaining a significant, yet undisclosed, percentage of the Manufacturers Payments, (b) using the inflated list price to generate profits from pharmacies, and (c) relying on the inflated list price to drive up the PBMs' margins through their own mail-order pharmacies.

1. The PBMs Pocket a Substantial Share of Manufacturers' Secret Payments

473. The first way in which the PBMs profit from the Insulin Pricing Scheme is by keeping a significant portion of the secret Manufacturer Payments.

474. The amount that the Manufacturers pay back to the PBMs has increased over time both in real dollars and as a proportion of the ever-increasing list prices.

475. Historically, contracts between PBMs and payors allowed the PBMs to keep most or all of the rebates they received, rather than forwarding them to the payor.

[114] Karen Van Nuys, *et al*., *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018*, JAMA Network (Nov. 5, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932 (last visited Jan. 15, 2023).

476. Over time, payors secured contract provisions guaranteeing payment to them of all or some portion of the rebates paid by the Manufacturers to the PBMs. Critically, however, "rebates" are only one aspect of the total secret Manufacturer Payments, particularly as "rebates" are narrowly defined and qualified by vague exceptions in the PBM Defendants' contracts with payors.

477. Indeed, as described in the Senate Insulin Report, the PBMs and Manufacturers coordinate to determine the contract options made available to payors: "Contracts between PBMs and manufacturers provide a menu of options from which their health plan clients can choose certain terms and conditions."[115]

478. The contracts between the PBMs and Manufacturers also "stipulate terms the plans must follow regarding factors such as formulary placement and competition from other drugs in the therapeutic class."[116] Thus, the Manufacturers ultimately played a role in dictating the terms and conditions of the contracts that payors like Plaintiff entered into with PBMs. Of course, the payors were not involved in the coordination or the negotiation of the contracts between the PBMs and Manufacturers, and the PBMs disclosed only the fact that such relationships may exist. But the terms of the contracts, the consideration exchanged between the PBMs

[115] Senate Insulin Report at 40.
[116] *Id.* at 44.

and Manufacturers, and the means of reaching these determinations all were—and remain—shrouded in secrecy.

479. The PBM and Manufacturer Defendants thus created a "hide-the-ball" system where payors like Plaintiff are not privy to rebate negotiations or contracts between the Manufacturers and the PBMs. The consideration exchanged between them (and not shared with payors) is continually labeled and relabeled. As more payors moved to contracts that required PBMs to remit some or all of the manufacturer "rebates" through to the payor, the PBMs renamed the Manufacturer Payments to shield them from scrutiny and from their payment obligations. Payments once called "rebates" were then termed "administrative fees," "volume discounts," "service fees," "inflation fees," or other industry terms designed to obfuscate the substantial sums being secretly exchanged between the PBM Defendants and the Manufacturers.

480. Just last year, the Senate Commerce, Science and Transportation Committee released testimony from David Balto—a former antitrust attorney with the DOJ and Policy Director for the FTC's Bureau of Competition—from a hearing on fairness and transparency in drug pricing. Mr. Balto's testimony describes how PBMs "transformed from 'honest brokers' supposedly negotiating with drug companies to obtain lower costs for insurers and patients into oligopolists using the

rebates they extract from drug manufacturers and pharmacies to enrich themselves."

He further testified:

> The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. In the past decade, PBM profits have increased to $28 billion annually.. . . . PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information. PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret." Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.[117]

481. The renamed, and secret, Manufacturer Payments are substantial. The use of "administrative fees" instead of "rebates" is one example. A heavily redacted complaint filed by Defendant Express Scripts in 2017 revealed that Express Scripts retains up to thirteen times more in "administrative fees" than it remits to payors in rebates.[118] In fact, administrative fees can dwarf rebates. In just one alleged invoice Express Scripts was seeking payment for in that lawsuit, "administrative fees" were more than three-and-a-half times the amount billed for formulary rebates and price

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[117] https://www.competitionpolicyinternational.com/pbms-the-middlemen-who-drive-up-drug-costs/ (last visited July 3, 2023).

[118] *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. 2017). Balto, *supra* note 97.

protection rebates *combined*.[119]

482. Although the proportion of rebates retained by PBMs remains a secret, commentators have suggested that PBMs "designate as much as twenty-five or thirty percent of the negotiated rebates as fees to avoid sharing the rebates."[120]

483. A review of Texas-mandated PBM disclosures also showed that PBMs retain a much greater percentage of manufacturer rebates than they lead on.[121] Under Texas law, certain PBMs are required to report "aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers." Between 2016 and 2021, the PBMs reported that they retained between 9% and 21% of total manufacturer payments.[122]

484. In an attempt to quantify the revenue PBMs receive from retained rebates, a 2023 report found that PBM compensation from rebates and other

[119] *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. 2017); Balto, *supra* n.82.

[120] Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale Law & Policy Review, https://openyls.law.yale.edu/bitstream/handle/20.500.13051/17295/auto_convert.pdf?sequence=3&isAllowed=y (last visited Apr. 20, 2024).

[121] Adam Fein, *Texas Shows Us Where PBMs' Rebates Go*, Drug Channels (Aug. 9, 2022), https://www.drugchannels.net/2022/08/texas-shows-us-where-pbms-rebates-go.html (last visited Apr. 20, 2024).

[122] *Id.*

kickbacks doubled between 2018 and 2022, from $3.8 billion to $7.6 billion.[123] "This growth was fueled by increases in traditional administrative fees as well as the emergence of new data and PBM contracting entity fees."[124] Administrative fees, the report estimated, grew from $3.8 billion in 2018 to $5.8 billion in 2022.

485. These so-called administrative fees typically are based on a percentage of the drug price—as opposed to a flat fee—such that even if the actual "administrative" cost associated with processing two drugs is the same, the "administrative fee" would be correspondingly higher for the higher-priced drug, which again creates (by design) a perverse incentive to give preference to more expensive drugs. Moreover, the PBM Defendants' contracts with payors narrowly define "rebates" by tying them to patient drug utilization. Thus, rebates for formulary placement (which are not tied to patient drug utilization) are characterized as "administrative fees" that are not remitted to payors. Such payments are beyond a payor's contractual audit rights because those rights are limited to "rebate" payments and these "administrative fees" have been carved out from the definition of "rebates."

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[123] Eric Percher, Trends in Profitability and Compensation of PBMs and PBM Contracting Entities, Nephron Research (Sept. 18, 2023), https://nephronresearch.bluematrix.com/sellside/AttachmentViewer.action?encrypt=1c65fc0e-f558-4f1d-891f-21c196a9f1ad&fileId=7276_04a77b17-d298-48a2-bd15-1c5ed22a6984&isPdf=false.

[124] *Id.*

486. The opaque nature of these arrangements between the Manufacturers and PBM Defendants also makes it impossible for a given payor to discover, much less assess or confront, conflicts of interest that may affect it or its members. The Senate Insulin Report observed with respect to these arrangements: "Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers."[125]

487. Not surprisingly, the PBMs have gone to great lengths to obscure these renamed Manufacturer Payments to avoid scrutiny from payors and others.

488. For example, as to the Manufacturer Payments now known as "inflation fees," the PBMs often create a hidden gap between how much the Manufacturers pay them to increase their prices and the amount in "price protection guarantees" that the PBMs agree to pay back to their client payors.

489. In particular, the Manufacturer Defendants often pay the PBM Defendants "inflation fees" if they increase the price of their diabetes medications. The thresholds for these payments are typically set at around 6% to 8%—if the Manufacturer Defendants raise their prices by more than the set percentage during a specified time period, then they pay the PBM Defendants an additional "inflation fee" (based on a percentage of the list prices).

[125] Senate Insulin Report at 4.

490. For many of their clients, the PBMs have separate "price protection guarantees," providing that if the overall drug prices for that payor increase by more than a set amount, then the PBMs will remit a portion of the amount to the client.

491. The PBMs set these "price protection guarantees" at a higher rate than the thresholds that trigger the Manufacturers' "inflation fees," usually around 10%-15%.

492. Thus, if the Manufacturers increase their list prices more than the 6% (or 8%) inflation fee rate, but less than the 10%-15% client price protection guarantee rate, then the PBMs keep all of these "inflation fee" payments. This is a win-win for the Manufacturers and PBM Defendants—they share and retain the entire benefit of these price increases, while the PBM contracts with payors imply that payors are protected from price hikes by their price protection guarantees.

493. The PBM Defendants also hide the renamed Manufacturer Payments with "rebate aggregators." Rebate aggregators, sometimes referred to as rebate group purchasing organizations ("GPOs"), are entities that negotiate for and collect payments from drug manufacturers, including the Manufacturer Defendants, on behalf of a large group of PBMs (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

494. These rebate aggregators are often affiliated with or owned by the PBM Defendants, such as Ascent Health Services (Express Scripts), Coalition for

Advanced Pharmacy Services and Emisar Pharma Services (OptumRx), and Zinc (CVS Caremark).

495. The PBM Defendants carefully guard the revenue streams from their rebate aggregator activities, concealing them through complex contractual relationships and not reporting them separately in their quarterly SEC filings.

496. Certain rebate-aggregator companies are located offshore, including, for example, in Switzerland (Express Scripts affiliate Ascent Health) and Ireland (Emisar Pharma Services), thereby precluding adequate oversight.

497. As summarized by the recent Community Oncology Alliance report:[126]

> PBMs have increasingly "delegated" the collection of manufacturer rebates to "rebate aggregators," which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and without telling plan sponsors. . . . Even some of the major PBMs (i.e., the "Big Three" PBMs) sometimes find themselves contracting with other PBMs' rebate aggregators for the collection of manufacturer rebates. . . . In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (i.e., contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.

498. For example, a 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from 2013 to 2015 concluded that the auditor was unable to verify the percentage of rebates OptumRx remitted to its

[126] Community Oncology Alliance, *supra* note 67.

client payor because OptumRx would not allow the auditor access to its rebate contracts. The audit report explained:

> Optum[Rx] has stated that it engaged the services of an aggregator to manage its rebate activity. Optum[Rx] shared that under this model, they are paid by their aggregator a certain amount per prescription referred. Then, the aggregator, through another entity, seeks rebates from the drug manufacturers, based upon the referred [Payor Client] prescription utilization, and retains any rebate amounts that may be received. Optum[Rx] states that they have paid [Payor Client] all amounts it has received from its aggregator, and that they do not have access to the contracts between the aggregator (and its contractors) and the manufacturer. However, our understanding is that Optum[Rx] has an affiliate relationship with its aggregator.[127]

499. A footnote in the audit report clarifies that "Optum[Rx] contracted with Coalition for Advanced Pharmacy Services (CAPS), and CAPS in turn contracted with Express Scripts, Inc. (ESI)."[128]

500. In other words, according to this report, OptumRx contracts with its own affiliate aggregator CAPS, which then contracts with OptumRx's co-conspirator Express Scripts, which then contracts with the Manufacturers for rebates related to OptumRx's client's drug utilization. OptumRx then uses this complex relationship to mask the amount of Manufacturer Payments generated from its client's utilization.

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[127] Laura Rogers & Stacey Thomas, Broward County Florida, Audit of Pharmacy Benefit Management Services Agreement, No. 18-13 (Dec. 7, 2017), available at https://cragenda.broward.org/docs/2018/CCCM/20180109_555/25990_2017_1212%20Exh1_OptumRx%20-%20Revised%20Item.pdf (last visited July 3, 2023).

[128] *Id.* n.3.

501. A subsequent audit by the same local entity—covering the period September 2017 to September 2018, concluded:

> Several material weaknesses in Broward's agreement with Optum were identified, many of which are commonplace across pharmacy benefit manager agreements in general. Due to contract weaknesses, a comparison of Broward's PBM agreement, including rebate amounts received, to the Consultant's marketplace data is not feasible. Broward could save an estimated $1,480,000 per year in net prescription drug benefit expenses (based upon minimum rebate guarantees) by switching from its current flawed agreement with Optum, to an agreement with its Coalition, which offers clearly defined terms, increased rebate guarantees and cost saving requirements.[129]

Among other "loopholes" discovered in the contract were several "flawed" (i.e., vague and manipulable) definitions, including (a) the definition of "Rebates," which "allows the exclusion of monies that should be included" and (b) limitations with respect to "Pass Through Transparency Pricing."

502. The January 2021 Senate Insulin Report summarized the Senate Finance Committee's findings from its two-year probe into the Insulin Pricing Scheme and contained the following observation on these rebate aggregators:

> [T]he recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such

[129] Broward County, Florida, *Analysis of Broward County's Prescription Drug Coverage*, https://www.broward.org/Auditor/Reports/Reports/082019_Exh1_BCRxDrug_19-15.pdf (last visited July 3, 2023).

> fees through a Swiss-based group purchasing organization (GPO), Ascent Health. While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules. New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.[130]

503. Federal regulations governing Medicare attempt to capture all possible forms of Direct or Indirect Remuneration (DIR) to PBMs (and plan sponsors), defining the term as "any form of price concession" received by a plan sponsor or PBM "from any source," including "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action," and other price concessions or similar benefits and specifically including "price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale."[131] The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) considers all of the following as DIR: rebates, grants, reduced price administrative services, PBM-retained rebates, PBM rebate guarantee amounts, all post-point of sale payments by pharmacies that are not

[130] Senate Insulin Report at 83.

[131] CMS, *Final Medicare Part D DIR Reporting Guidance for 2021* at 7, https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf (last visited Jan. 15, 2023).

included in the negotiating price including dispensing incentive payments, prompt pay discounts, and payment adjustments. On the other hand, "bona fide service fees from pharmaceutical manufacturers" and "remuneration for administrative services with no impact on the sponsor's or PBM's drug cost (e.g., PBM incentive payments)" are *not* considered DIR *but only to the extent they reflect fair market value for services rendered.*[132]

504. Because the PBM Defendants retain and conceal most of the secret Manufacturer Payments that they receive, they are able to make significant profits on the Insulin Pricing Scheme.

505. Even when payor clients receive a portion of the Manufacturer Payments from their PBM, the payors are significantly overcharged, given the extent to which Defendants have deceptively and egregiously inflated the prices of the at-issue drugs.

2. The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies

506. A second way the PBM Defendants profit off the Insulin Pricing Scheme is by using the Manufacturers' inflated price to derive profit from the pharmacies with whom they contract nationwide.

[132] *Id.* at 6-7.

507. Each PBM Defendant decides which pharmacies are included in the PBM's network and how much it will reimburse these pharmacies for each drug dispensed.

508. The PBMs pocket the spread between the amount that the PBMs are paid by their clients for the at-issue drugs (which are based on the prices generated by the Insulin Pricing Scheme) and the amount the PBM reimburses the pharmacy (which often is less). In other words, the PBMs charge a client payor more for a drug than the PBM pays the pharmacy and pockets the difference.

509. More specifically, the PBM Defendants negotiate with their client payors a reimbursement rate that the client pays the PBM for each prescription drug dispensed by a pharmacy. The PBM Defendants negotiate a separate rate that they pay to pharmacies for each drug dispensed.

510. These rates are tied to AWP. For example, a PBM may purchase an insulin from the pharmacy at a rate of AWP-15%, and the client may reimburse the PBM at a rate of AWP-13%. The PBM pockets the spread (2% of AWP in this example) between the rates.

511. Because the PBM Defendants' revenue from the spread pricing is tied to AWP, the higher the AWP, the greater the amount of money made by the PBMs. In the above example, if the AWP is $100 for a drug, the PBM would make $2 on the

spread, but if the AWP is $1000 for the same drug, the PBM would make $20 on the spread from the same sale (AWP-15% = $850; AWP-13% = $870).

512. When a PBM is affiliated with a retail pharmacy, the PBM earns the entire retail margin in addition to the pricing spread described above.

513. The PBM Defendants, therefore, like the Manufacturers, directly benefit from inflated insulin prices.

514. In addition, because the PBM Defendants' client payors pay for thousands of different prescription drugs, the client payors cannot practically keep track of the AWP for each prescription drug on a given formulary or how those prices change over time. The client payors, therefore, are unlikely to independently observe the AWP inflation resulting from the Insulin Pricing Scheme. And the PBM Defendants have no incentive to alert their client payors to increasing AWPs since the PBM Defendants directly profit from those increases.

515. In addressing this form of spread pricing, the National Association of Insurance Commissioners states: "Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement."[133]

[133] NAIC, Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation—NAIC White Paper Draft as of April 16, 2023, available at: https://content.naic.org/sites/default/files/inline-files/NACDS%20Comments_0.pdf (last visited Aug. 22, 2023).

516. A bipartisan bill introduced in the Senate in 2022 (the Pharmacy Benefit Manager Transparency Act—S. 4293)—would have criminalized this practice of spread pricing, which the bill defined as "[c]harg[ing] a health plan or payer a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug's ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference." The bill has not yet been enacted.[134]

517. The PBMs' industry-funded trade association PCMA, spent $7.8 million on federal lobbying in 2021 and more $6 million through the third quarter of 2022.[135]

518. The PBMs often disclose the general concept of spread pricing to payors, but only in vague terms that require no accountability and because the spread-pricing revenue is not defined as a "rebate" in PBM contracts with payors and it falls outside payors' audit rights.

519. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from the PBM Defendants to take into account the cost effectiveness of a drug, and no

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[134] https://www.govtrack.us/congress/bills/117/s4293 (last visited Jan. 10, 2023). A new PBM Transparency Act (S.127) was introduced in July 3, 2023.

[135] https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2021&id=D000028342 (2021); https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2022&id=D000028342 (2022) (last visited July 3, 2023).

communication to either the payor or the pharmacy to let them know if they are getting a fair deal.

520. The higher the Manufacturers' list prices, the more money the PBMs make off this spread. At the same time, a Beneficiary's out-of-pocket co-pay or deductible cost often is more than if the client had simply paid cash outside of his or her plan. On top of this, the PBM contracts generally allow no rebates to payors where the Beneficiary is responsible for 100% of the drug cost, e.g., under his or her deductible.

521. The PBM Defendants also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR (Direct or Indirect Remuneration) fees, based on the list prices—and again, the higher the list price for each diabetes medication sold, the greater the fees the PBMs generate. They also apply "retrospective" discounts so, for example, a payor's (and member's co-pay or deductible) cost may be $100, but the price may be discounted post-purchase between the PBM and the (often self-owned) pharmacy to $90, with the spread going to the PBM.

522. CMS addressed these and similar DIR issues in a proposed rule in 2017. While noting the growth of "pharmacy price concessions" that "are negotiated between pharmacies and their sponsors or PBMs," CMS nevertheless concluded:

> When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might

> see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent . . . .[136]

CMS expressed further concern that when rebates and other price concessions are not reflected in the negotiated point-of-sale drug price, it "can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries . . . ."[137]

523. So PBM Defendants make money "coming and going." In a pre-PBM world, a competitively priced drug might have a (hypothetical) net cost to a health plan of $50, and that is what it paid. PBMs enter the picture and coordinate with Manufacturers to increase the list price to $150. The PBMs then "negotiate" the inflated price down to $100 and take a $50 rebate, some of which may be forwarded to the payor, whose net cost is less than the inflated list price, but whose real-world cost is considerably more than if the PBMs were not involved.

524. At the same time, the PBM receives "administrative fees" for including certain drugs on its formularies, which are not considered "rebates." The PBM also

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[136] Medicare Program; Contract Year 2019 Policy and Technical Changes, 82 Fed. Reg. 56336 (Nov. 29, 2017), https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf.

[137] *Id.*

receives "service fees" or other payment for "administrative services" provided to the Manufacturers such as "formulary compliance initiatives," "education services," or the sale of non-patient identifiable claim information. All of these revenue streams are outside the typical definition of "rebates" found in contracts between the PBM Defendants and payors. The PBMs then charge payors administrative fees for providing pharmacy benefit management services and charges for drug costs (a/k/a ingredient costs) and per-prescription dispensing fees, as well as additional administrative fees for services not included in the PBM's general administrative obligations. The PBM then receives rebates and/or discounts (pre-purchase or post-purchase) from the pharmacies, which the PBM often owns. These too are excluded from the definition of "rebates." These and other vaguely described revenue streams are sometimes disclosed, but only in hazy, overly generalized terms. And they are beyond a payor's contractual rights to audit for "transparency" purposes because they are not defined "rebates." Additionally, the PBM may take months to pay rebates to payors and the PBM retains all interest on, and the time-value of, the rebates pending payment. This is one example of a PBM "disclosure" excerpted from a payor's PBM contract with Express Scripts:

> This disclosure provides an *overview* of the *principal* revenue sources of Express Scripts, Inc. and Medco Health Solutions, Inc. (individually and collectively referred to herein as "ESI"), as well as ESI's affiliates. In addition to administrative and dispensing fees paid to ESI by our clients for pharmaceutical benefit management ("PBM") services, ESI

> and its affiliates derive revenue from other sources, including arrangements with pharmaceutical manufacturers, wholesale distributors, and retail pharmacies. *Some* of this revenue relates to utilization of prescription drugs by members of the clients receiving PBM services. ESI *may* pass through certain manufacturer payments to its clients or *may* retain those payments for itself, depending on the contract terms between ESI and the client. . . . Formulary rebate amounts vary based on the volume of utilization as well as formulary position applicable to the drug or supplies, and adherence to *various* formulary management controls, benefit design requirements, claims volume, and *other similar factors*, and *in certain instances* also *may* vary based on the product's market-share. ESI *often* pays an amount equal to all or a portion of the formulary rebates it receives to a client based on the client's PBM agreement terms. ESI retains the financial benefit of the use of any funds held until payment of formulary rebate amounts is made to the client. In addition, ESI provides administrative services to formulary rebate contracted manufacturers, which include, *for example*, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. (emphasis added)

525. Payors have no access to, and no knowledge of, the intricacies of the dealings between the PBM Defendants and the Manufacturers that are shrouded by such vague "disclosures" (which vary in detail, but not in substance, in all three of the PBM Defendants' adhesive contracts). These disclosures could be summed up in a single sentence: "We pass along 'rebates' to client payors, except when we don't."

3. The Insulin Pricing Scheme Increases PBM Mail-Order Profits

526. Another way PBM Defendants profit from the Insulin Pricing Scheme is through their mail-order pharmacies. The higher the price that PBM Defendants can get customers to pay for diabetes medications, the greater the profits PBM Defendants realize through their mail-order pharmacies.

527. Because the PBMs base the prices they charge for the at-issue diabetes medications on the Manufacturers' prices, the more the Manufacturers inflate their prices, the more money the PBMs make.

528. When a PBM has its own mail-order pharmacy, its profits are even greater than when they are dispensed through its retail network pharmacies. When a PBM dispenses prescription drugs through its own mail-order pharmacy, it captures the entire retail margin as increased by the Insulin Pricing Scheme.

529. The PBM Defendants have colluded with the Manufacturers so that the PBMs often know when the Manufacturers are going to raise their prices. The PBMs purchase a significant volume of the at-issue drugs before the price increase goes into effect. Then, after the Manufacturers raise their price, the PBMs charge their mail-order customers based on the increased prices and pocket the difference. The PBMs make significant amounts of money through this arbitrage scheme.

530. The PBM Defendants also charge the Manufacturer Defendants fees related to their mail-order pharmacies, such as pharmacy supplemental discount fees,

which are directly tied to the Manufacturers' price. Once again, the higher the price is, the more money the PBMs make on these fees.

531. In sum, each way in which the PBM Defendants make money on diabetes medications is tied directly to coordination with the Manufacturers to establish artificially higher prices and inducing ever-increasing secret Manufacturer Payments. The PBMs are not lowering the price of diabetes medications as they publicly represent. On the contrary, they are making billions of dollars at the expense of payor clients and their plan participants by fueling these skyrocketing prices.

K. Plaintiff Purchased At-Issue Drugs Directly from Defendants

532. As a government employer, Plaintiff serves its residents by providing public safety, emergency management, and health services, among other vital roles. As more federal and state responsibilities are passed on to local government, Plaintiff has a growing list of demands on a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Plaintiff's overall budget and, in turn, negatively impact its ability to provide necessary services to the community.

533. One benefit Plaintiff provides its Plan Participants is payment for a large portion of their pharmaceutical purchases. In this role, Plaintiff spent significant amounts on the at-issue diabetes medications during the relevant period.

534. Because Plaintiff maintains a self-funded plan, it does not rely on a third-party insurer to pay for its insured's medical care, pharmaceutical benefits, or prescription drugs. Rather, Plaintiff directly contracts with, and directly pays, PBMs (and their affiliated pharmacies) for pharmaceutical benefits and prescription drugs, including the at-issue medications.

535. Plaintiff is the only named party that pays the full purchase price for the at-issue drugs, and the only named party that has not knowingly participated in the Insulin Pricing Scheme. Neither the PBM Defendants nor the Manufacturer Defendants suffer losses from the Insulin Pricing Scheme. As part of purchasing the at-issue drugs from the PBMs, Plaintiff directly pays the PBMs artificially inflated costs resulting from the Insulin Pricing Scheme, including "administrative fees," "inflation fees," "discounts," and more—all of which are associated with Plaintiff's purchase of the at-issue drugs from the PBM Defendants. Because the at-issue drugs are potentially life-saving medications, and because the Defendants control the market for these drugs, Plaintiff has no choice but to pay these exorbitant, artificially inflated prices directly to PBM Defendants.

536. To administer its health plans' pharmaceutical program, Plaintiff relies on the PBMs as administrative agents, for the supposed purpose of limiting its administrative burden and controlling pharmaceutical drugs costs.

537. At different times during the relevant period, Plaintiff relied on Defendants Express Scripts, OptumRx, and CVS Caremark, to provide PBM services to its health plans. These PBM services included developing and offering formularies for Plaintiff's prescription plan, constructing and managing Plaintiff's pharmacy network (which included the PBMs' retail and mail-order pharmacies), processing pharmacy claims, and providing mail-order pharmacy services to Plaintiff.

538. In providing PBM services to Plaintiff, including developing and offering formularies for Plaintiff's prescription plan, constructing and managing Plaintiff's pharmacy network (which included the PBMs' retail and mail-order pharmacies), processing pharmacy claims, and providing mail-order pharmacy services, Defendants Express Scripts, OptumRx, and CVS Caremark—in direct coordination with the Manufacturer Defendants and utilizing the false prices generated by the Insulin Pricing Scheme—set the amounts Plaintiff paid for the at-issue medications. Plaintiff paid Express Scripts, OptumRx, and CVS Caremark directly for the at-issue drugs and paid those PBM Defendants to manage pharmacy benefits related to the at-issue drugs.

L. Defendants Deceived Plaintiff

539. At no time has either Defendant group disclosed the Insulin Pricing Scheme or the false list prices produced by it.

1. The Manufacturer Defendants Deceived Plaintiff

540. At all times during the relevant period, the Manufacturer Defendants knew that the list prices, net prices, and payors' net costs (purchase prices) generated by the Insulin Pricing Scheme were false, excessive, and untethered to any legal, competitive, or fair market price.

541. The Manufacturer Defendants knew that these prices did not bear any rational relationship to the actual costs incurred or prices realized by Defendants, did not result from transparent or competitive market forces, and were artificially and arbitrarily inflated for the sole purpose of generating profits for Defendants.

542. The insulin market, and Defendants' business arrangement relating to it, exhibits the key features of an oligopoly (*see* Figure 20)—the concentration of numerous competitors into a small group of firms that dominates the market, high barriers to entry, the ability to set and control prices, firm interdependence, and maximal revenues.

543. The Manufacturer Defendants also knew that payors, including Plaintiff, relied on the false list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs.

544. The Manufacturer and PBM Defendants further knew that Plaintiff—like any reasonable consumer and particularly one with fiduciary obligations to its Plan Participants—wanted and expected to pay a price reflecting the lowest fair

market value for the drugs (which was not necessarily the same as the lowest price in the market, given that all prices were inflated due to the Insulin Pricing Scheme).

545. Despite this knowledge, the Manufacturer Defendants published list prices generated by the Insulin Pricing Scheme throughout the United States and Virginia through publishing compendia, in various promotional and marketing materials distributed by entities downstream in the drug supply chain, and directly to pharmacies, who then used these prices to set the amount that the pharmacies charged for the at-issue drugs.

546. The Manufacturer Defendants also published these prices to the PBMs, who then used them to charge diabetics and payors for the at-issue drugs.

547. By publishing their prices in every U.S. state, the Manufacturers held each of these prices out as a reasonable price on which to base the prices payors actually pay for the at-issue drugs.

548. These representations are false. The Manufacturer Defendants knew that their artificially inflated list prices were not remotely related to their cost, their fair market value in a competitive market, or the net price received for the at-issue drugs.

549. During the relevant period, the Manufacturer Defendants have published prices in every state within the United States in the hundreds of dollars per dose for the same at-issue drugs that would have been profitable to Manufacturers at prices less than $10 per dose.

550. The Manufacturer Defendants also have publicly represented that they price the at-issue drugs according to each drug's value to the health care system and the need to fund innovation. For example, briefing materials prepared for Dave Ricks, Eli Lilly CEO, as a panelist at the 2017 Forbes Healthcare Summit included "Reactive Key Messages" on pricing that emphasized the significant research and development costs for insulin. During the relevant period, executives from Sanofi and Novo Nordisk also falsely represented that research and development costs were key factors driving the at-issue price increases.[138]

551. Contrary to the Manufacturer Defendants' representations, between 2005 and 2018, Eli Lilly spent $680 million on R&D costs related to Humalog while earning $31.35 billion in *net* sales during that same time period. In other words, Eli Lilly made more than 46 times its reported R&D costs on Humalog during this portion of the relevant period, i.e., R&D costs amounted to about 2% of *net* sales (whereas R&D costs for pharmaceuticals typically amount to around 20% of *total* revenues). Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.[139]

552. The Senate Insulin Report found that the PBMs consider insulins to be "interchangeable" from "a clinical perspective" and that Manufacturers "focus their

[138] Drug Pricing Investigation at PDF 188-94.
[139] *Id.*

R&D efforts on new insulin-related devices, equipment, and other mechanical parts that are separate from insulin's formulation."[140]

553. A House Oversight Committee staff report concluded that "drug companies' claims that reducing U.S. prescription drug prices will harm innovation is overblown" and that "[m]any drug companies spent a significant portion of their R&D budget on finding ways to suppress generic and biosimilar competition while continuing to raise prices, rather than on innovative research."[141]

554. In sum, the Manufacturer Defendants affirmatively withheld the truth from Plaintiff and specifically made misrepresentations in furtherance of the Insulin Pricing Scheme and to induce Plaintiff's reliance to purchase the at-issue drugs.

2. The PBM Defendants Deceived Plaintiff

555. The PBM Defendants ensured that the Manufacturer Defendants' artificially inflated list prices harmed diabetics and payors by preferring the highest-priced at-issue drugs for preferred formulary placement and by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

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[140] Senate Insulin Report at 5, 17.

[141] U.S. House of Reps., *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends and Executive Compensation* (July 2021) at PDF 3, https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf (last visited Jan. 10, 2023).

556. The PBM Defendants perpetuate the use of the artificially inflated insulin prices because it allows them to obscure the actual price any entity in the drug pricing chain is paying for the at-issue drugs. This lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme, and to profit therefrom at the expense of payors nationwide.

557. At all times throughout the relevant period, the PBMs have purposefully, consistently and routinely misrepresented that they negotiate with Manufacturer Defendants and construct formularies for the benefit of payors and patients by lowering the price of the at-issue drugs and by promoting the health of diabetics. Representative examples include:

a. CVS Caremark has for the past decade stated in its annual reports that its design and administration of formularies are aimed at reducing the costs and improving the safety, effectiveness and convenience of prescription drugs. CVS Caremark has further stated that it maintains an independent panel of doctors, pharmacists and other medical experts to review and approve the selection of drugs based on safety and efficacy for inclusion on one of Caremark's template formularies and that CVS Caremark's formularies lower the cost of drugs.

b. Express Scripts has consistently represented that it works with clients, manufacturers, pharmacists and physicians to increase efficiency in the

drug distribution chain, to manage costs in the pharmacy benefit chain and to improve members' health outcomes. Its annual reports consistently claim that in making formulary recommendations, Express Scripts' Pharmacy & Therapeutics Committee considers the drug's safety and efficacy, without any information on or consideration of the cost of the drug, including any discount or rebate arrangement that Express Scripts negotiates with the Manufacturer, and that Express Scripts fully complies with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.

c. OptumRx has stated in its annual reports over the past decade that OptumRx's rebate contracting and formulary management assist customers in achieving a low-cost, high-quality pharmacy benefit. It has consistently claimed that it promotes lower costs by using formulary programs to produce better unit costs, encouraging patients to use drugs that offer improved value and that OptumRx's formularies are selected for health plans based on their safety, cost and effectiveness.[142]

[142] *See, e.g.*, CVS Health Annual Reports (Form 10-K) (FY 2010-2019); OptumRx Annual Reports (Form 10-K) (FY 2010-2019); Express Scripts Annual Reports (Form 10-K) (FY 2010-2017).

558. In addition to these general misrepresentations, the PBM Defendants have during the relevant period purposefully, consistently, and routinely made misrepresentations about the at-issue diabetes medications. Representative examples include:

a. In a public statement issued in November 2010, CVS Caremark represented that it was focused on diabetes to "help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately $3.3 million a year in medical expenditures."[143]

b. In 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark, stated on national television that "CVS is working to develop programs to hold down [diabetes] costs."[144]

[143] Chain Drug Review, *CVS Expands Extracare for Diabetes Products* (May 11, 2010), https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/ (last visited Jan. 15, 2023).

[144] CBS News, Diabetes Epidemic Growing (June 22, 2010, 11:29 AM), https://www.cbsnews.com/news/diabetes-epidemic-growing/ (last visited Jan. 15, 2023).

c. In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products "is one way the company helps manage costs for clients."[145]

d. In 2017, Express Scripts' CEO, discussing a program involving insulin, "disputed the idea that Express Scripts contributes to rising drug costs."[146]

e. In 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts, said in an interview with a national publication that "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . . [Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease."[147] Mr. Stettin also claimed that Express Scripts "broaden[s]

[145] Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, WSJ (Nov. 8, 2012), Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, WSJ (Nov. 8, 2012), http://online.wsj.com/article/SB10001424127887324439804578107040729812454.html (last visited July 3, 2023).

[146] Katie Thomas, *Express Scripts to Offer Cheaper Drugs for Uninsured Customers*, N.Y. TIMES, May 8, 2017, available at https://www.nytimes.com/2017/05/08/health/express-scripts-drug-prescriptions-prices.html (last visited Apr. 18, 2024).

[147] https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launches-program-to-control.html (last visited July 3, 2023).

insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."[148]

f. In a 2018 Healthline interview, Mark Merritt, long the President of the PBM trade association, PCMA, misrepresented that: "[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices."[149]

g. CVS Caremark's Chief Policy and External Affairs Officer claimed in the April 2019 hearings that CVS Caremark "has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers' price on behalf of employers, unions, government programs, and beneficiaries that we serve."[150]

h. Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for "insulin products . . . we negotiate with brand manufacturers to obtain significant

[148] Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs,* St. Louis Bus. J. (Aug. 31, 2016), https://drugstorenews.com/pharmacy/express-scripts-implements-latest-diabetes-care-value-program (last visited July 3, 2023).

[149] Dave Muoio, *Insulin Prices: Are PBMs and Insurers Doing Their Part?*, Population Health Learning Network (Dec. 2016), https://www.hmpgloballearningnetwork.com/site/frmc/article/insulin-prices-are-pbms-and-insurers-doing-their-part (last visited Jan. 15, 2023).

[150] *Priced Out of a Lifesaving Drug* at lines 715-18.

discounts off list prices on behalf of our customers."[151] In May 2023, OptumRx's CEO, Heather Cianfrocco, told the U.S. Senate Committee on Health, Education, Labor, and Pensions that OptumRx "has been at the forefront of efforts to improve access to affordable insulin and provide comprehensive care to patients with diabetes."[152]

i. The PBM-funded trade association PCMA's website acknowledges, "the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins," but then misleadingly claims that "PBMs work hard to drive down costs using formulary management and rebates."[153]

559. The PBM Defendants falsely represent that they negotiate with the Manufacturer Defendants to lower the price of the at-issue diabetes medications not only for *payors*, but also for diabetic *patients*. For example:

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[151] *Id*. at lines 903-06.

[152] Heather Cianfrocco Written Testimony, *The Need to Make Insulin Affordable for All Americans* (May 10, 2023), https://www.help.senate.gov/imo/media/doc/Cianfrocco%20Written%20Testimony%20HELP%20Committee%20_Final.pdf.

[153] PCMA, *PCMA on National Diabetes Month: PBMs Lowering Insulin Costs, Providing Support to Patients* (Nov. 16, 2020), https://www.pcmanet.org/pcma-on-national-diabetes-month-pbms-lowering-insulin-costs-providing-support-to-patients/ (last visited July 3, 2023); Visante, *Insulins: Managing Costs with Increasing Manufacturer Prices* (2020), https://www.pcmanet.org/wp-content/uploads/2020/08/PCMA_Visante-Insulins-Prices-and-Costs-.pdf.

a. Express Scripts' code of conduct, effective beginning in 2015, states: "At Express Scripts we're dedicated to keeping our promises to *patients and clients* . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable."[154]

b. Amy Bricker—former President of Express Scripts and PCMA board member—testified before Congress in April 2019: "At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs."[155]

c. Ms. Bricker also testified that "Express Scripts remains committed to . . . *patients* with diabetes and creating affordable access to their medications."[156]

d. OptumRx CEO John Prince testified to the Senate: "We *reduce the costs of prescription drugs* [and] we are leading the way to ensure that *those discounts directly benefit consumers*. . . . OptumRx's pharmacy care

[154] Express Scripts, *Code of Conduct*, https://www.express-scripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf (last visited July 3, 2023).

[155] *Priced Out of a Lifesaving Drug* at lines 803-06.

[156] *Id*. at lines 838-40.

services business is *achieving better health outcomes for patients*, *lowering costs* for the system, and *improving the healthcare experience for consumers*. . . . OptumRx negotiates better prices with drug manufacturers *for our customers and for consumers*.[157]

e. In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure "that the cost of a drug is aligned with the value it delivers in terms of *patient* outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings *Patients* Money initiative."[158]

f. The PCMA website touts PBMs as "the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs" and (contradicting the PBM representatives' Congressional testimony), that "when new manufacturers enter the market at a lower list price, PBMs use the competition to drive costs down."[159]

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[157] Senate Insulin Report—*Hearing Transcript* at 174, available at https://www.finance.senate.gov/imo/media/doc/435631.pdf (last visited July 3, 2023).

[158] CVS Health, *2017 Drug Trend Report* (Apr. 5, 2018), https://payorsolutions.cvshealth.com/insights/2017-drug-trend-report (last visited July 3, 2023).

[159] PCMA, *PBMs Reduce Insulin Costs: PBMs are working to improve the lives of patients living with diabetes and their families,* https://www.pcmanet.org/insulin-managing-costs-with-increasing-manufacturer-prices/ (last visited July 3, 2023).

560. Not only have the PBM Defendants intentionally misrepresented that they use their market power to save payors money, they have specifically and falsely disavowed that their conduct drives prices higher. Representative examples include:

a. On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated: "Drugmakers set prices, and we exist to bring those prices down."[160]

b. Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017: "Any suggestion that PBMs are causing prices to rise is simply erroneous."[161]

c. In 2017, Express Scripts' Wentworth went on CBS News to argue that PBMs play no role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."[162]

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[160] Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), https://www.stltoday.com/business/local/express-scripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef-5575-8b5c-95601ac51840.html (last visited July 3, 2023).

[161] Lynn R. Webster, *Who Is To Blame For Skyrocketing Drug Prices?*, The Hill (July 27, 2017, 11:40 AM), https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-to-blame-for-skyrocketing-drug-prices (last visited July 3, 2023).

[162] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/ (last visited July 3, 2023).

d. During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Chief Medical Officer Sumit Dutta answered, "we can't see a correlation just when rebates raise list prices."[163]

e. In 2019, when testifying Congress on the rising price of insulins, Amy Bricker—then with Express Scripts, now with CVS—testified, "I have no idea why the prices [for insulin] are so high, none of it is the fault of rebates."[164]

561. All of the PBM Defendants' public statements regarding insulin pricing have been consistent with the misrepresentations above. None has contradicted those misrepresentations, and none has revealed the Insulin Pricing Scheme.

562. Although Plaintiff's employees responsible for managing Plaintiff's health plans were not following the various Congressional hearings when they occurred and were not exposed to all of the misrepresentations detailed above, the public pronouncements by Defendants were consistent with those misrepresentations.

[163] *Priced Out of a Lifesaving Drug* at lines 1019-22.
[164] *Id*. at lines 1016-17.

563. Plaintiff's direct interactions with the PBM Defendants were consistent with those misrepresentations, which were made in furtherance of, and in order to conceal, the Insulin Pricing Scheme.

564. While bombarding Plaintiff with misrepresentations and half-truths, none of the PBMs revealed the details of their relationships with the Manufacturer Defendants or the existence of the Insulin Pricing Scheme.

565. Throughout the relevant period, the PBM Defendants have consistently and repeatedly represented that: (a) their interests are aligned with their payor clients; (b) they work to lower the price of the at-issue drugs and, in doing so, achieve substantial savings for diabetics and payors; and (c) monies they receive from manufacturers and their formulary choices are for the benefit of payors and diabetics.

566. Indeed, the PBM Defendants have promised to avoid conflicts of interest. For example, the PCMA has Principles of Professional and Ethical Conduct to which all PCMA members, including the three PBM Defendants, have agreed.[165] This code of ethics requires the PBM Defendants to "[a]void any and all conflicts of interest and advise all parties . . . of any situations where a conflict of interest exists."[166]

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[165] *Principles of Professional and Ethical Conduct*, PCMA, https://www.pcma.org/about/principles-of-professional-and-ethical-conduct/ (last visited Apr. 20, 2024).

[166] *Id.*

567. Each PBM Defendant has also published a code of conduct requiring employees and entities to avoid conflicts of interest.[167] Despite these obligations, the PBM Defendants have substantial pecuniary interests that conflict with their duties to the City of Alexandria, Virginia. The PBM Defendants artificially inflate the price of insulin for their profit, to the detriment of payors, including Plaintiff.

568. The PBM Defendants understand that payors like Plaintiff rely on the PBMs to achieve the lowest prices for the at-issue drugs and to construct formularies designed to improve access to medications. Plaintiff did so.

569. Throughout the relevant period, the PBM Defendants also falsely claimed they are transparent about the Manufacturer Payments and that the amounts remitted (or not) to payors. In fact, the PBM Defendants' disclosures of their ties to the Manufacturer Defendants were vague, equivocal, and misleading. Their manner of defining "rebates" in payor contracts is misleading and subject to undefined and indeterminable conditions and exceptions. The PBM Defendants thereby facilitated and obtained secret Manufacturer Payments far above and beyond the amount of "rebates" remitted to payors.

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[167] Code of Conduct, Express Scripts, https://www.express-scripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf (last visited Apr. 20, 2024); Code of Conduct, CVS Caremark, https://media.corporate-ir.net/media_files/irol/99/99533/corpgov/codeofconduct03.pdf (last visited Apr. 20, 2024); Code of Conduct, UnitedHealth Group, https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/FWA_CoCs_2018.pdf (last visited Apr. 20, 2024).

570. The PBM Defendants' internal processes and accounting were and are abstruse and opaque, allowing them to overtly mislead the public and payors like Plaintiff.

571. In 2011, for example, OptumRx's President stated: "We want our clients to fully understand our pricing structure . . . [e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure."[168]

572. In a 2017 CBS News interview, Express Scripts' CEO represented, among other things, that Express Scripts was "absolutely transparent" about the Manufacturer Payments they receive and that payors "know exactly how the dollars flow" with respect to these Manufacturer Payments.[169]

573. When testifying before the Senate Finance Committee, CVS Executive Vice President Derica Rice stated, "[A]s it pertains to transparency overall, we at

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[168] UnitedHealth Group, *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards* (Sept. 13, 2011), https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html (last visited Jan. 11, 2023). *Also see, e.g.*, published version of press release at https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-by-OptumRx-Receives-4th-Consecutive-TIPPSSM-Certification-for-Pharmacy-Benefits-Transparency-Standards (last visited Jan. 11, 2023).

[169] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/ (last visited July 3, 2023).

CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf. . . . And transparency—today we report and fully disclose not only to our clients, but to CMS [Medicare]."[170]

574. At the same hearing, Steve Miller of Cigna (Express Scripts) testified: "we are really a strong proponent for transparency for those who pay for health care. So the patient should know exactly what they are going to pay. Our plan sponsors need to know exactly what is in their contract."[171]

575. John Prince of OptumRx chimed in: "Senator, if our discounts were publicly available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients."[172]

576. And when testifying before Congress in April 2019, Amy Bricker, then a Senior Vice President of Defendant Express Scripts, touted transparency with payors and echoed Mr. Prince's need for confidentiality around discounts:[173]

> Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate

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[170] Senate Insulin Report - *Hearing Transcript* at 28, 32, https://www.finance.senate.gov/imo/media/doc/435631.pdf (last visited July 3, 2023).

[171] *Id.* at 32.

[172] *Id.*

[173] *Priced Out of a Lifesaving Drug* at lines 2469-2506.

> for them is transparent to them. . . The reason I'm able to get the discounts that I can from the manufacturer is because it's confidential [to the public].
>
> ***
>
> Mr. Sarbanes. Yeah, because it is a secret. What about if we made it completely transparent? Who would be for that?
>
> ***
>
> Ms. Bricker. Absolutely not . . . [i]t will hurt the consumer. . . . prices will be held high.

577. As recently as May 2022, JC Scott—President of the PBM trade group PCMA—testified before the Senate Commerce Committee:

> PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes. PBMs negotiate with drug companies to lower prescription drug costs PBMs advocate for patients in the fight to keep prescription drugs accessible and affordable.

Mirroring the PCMA website (¶ 530f *supra*), Mr. Scott also testified, "The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs."[174]

578. During the relevant period PBM Defendants represented to Plaintiff that they constructed formularies and negotiated with the Manufacturer Defendants for

[174] https://www.pcmanet.org/jc-scott-testifies-before-a-senate-panel-about-pbm-value/ (last visited July 3, 2023).

the benefit of payors and patients to maximize drug cost savings while promoting the health of diabetics.

579. Throughout the relevant period, the PBMs consistently made similar misrepresentations directly to payors nationwide through bid proposals, member communications, invoices, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

580. All such representations are false—the Manufacturer and PBM Defendants in fact coordinated to publish the false prices and to construct the PBM formularies, causing the price of the at-issue drugs to skyrocket. For example:

a. In 2018, the United States spent $28 billion on insulin compared with $484 million in Canada. The average American insulin user spent $3490 on insulin in 2018 compared with $725 among Canadians.[175]

b. Diabetics who receive their medications from federal programs that do not utilize PBMs also pay significantly less. In December 2021, the United States House of Representatives Committee on Oversight and Reform issued its Drug Pricing Investigation Report finding that federal health care programs that negotiate directly with the Manufacturers (like

[175] Schneider, T., Gomes, T., Hayes, K. N., Suda, K. J., & Tadrous, M. (2022). Comparisons of Insulin Spending and Price Between Canada and the United States. *Mayo Clinic Proceedings*, *97*(3), 573–578. https://doi.org/10.1016/j.mayocp.2021.11.028.

the Department of Veterans Affairs), and which are thus outside the PBM Defendants' scheme, paid $16.7 billion less from 2011 through 2017 for the at-issue drugs than the Medicare Part D program, which relies on the PBM Defendants to set their at-issue drug prices.[176]

581. Defendants knew their representations were false when they made them and coordinated to affirmatively withhold the truth from payors, including Plaintiff.

582. Defendants concealed the falsity of their representations by closely guarding their pricing negotiations, structures, agreements, sales figures, and the flow of money and other consideration between them.

583. The Defendants have never revealed the full amount of any drug-specific Manufacturer Payments exchanged between them. Despite the claims of transparency to Plaintiff and to the public and despite Plaintiff's contracts with Express Scripts, OptumRx, and CVS Caremark, Plaintiff does not know, and cannot learn, of the full extent of the Manufacturer Payments and other agreements between PBMs and the Manufacturer Defendants.

584. The PBM Defendants do not disclose the terms of the agreements they make with the Manufacturers or the Manufacturer Payments they receive. Nor do

[176] https://www.fiercepharma.com/pharma/house-oversight-committee-blasts-pharma-for-outrageous-prices-and-anticompetitive-conduct (last visited July 3, 2023).

they disclose the details related to their agreements (formal or otherwise) with pharmacies. All those revenue streams are beyond the scope of the payors' contractual audit rights.

585. Further, although PBMs negotiate drug-specific rebates with Manufacturers,[177] the PBM rebate payments to payor clients and summaries of such payments are in the aggregate, rather than on a drug-by-drug basis. It is impossible for payors like Plaintiff to tease out drug-specific rebates, much less the other undisclosed Manufacturer Payments. This allowed the PBM Defendants to hide the large Manufacturer Payments that they receive for the at-issue diabetes medications.

586. The PBM Defendants have gone so far as to sue governmental entities to block the release of details on their pricing agreements with the Manufacturers and pharmacies.

587. Even when audited by payors, the PBM Defendants routinely refuse to disclose their agreements with the Manufacturers and pharmacies by relying on overly broad confidential agreements and claims of trade secrets and by erecting other unnecessary roadblocks and restrictions.

588. Plaintiff's Plan Participants have no choice but to pay prices flowing from the Manufacturers' inflated list prices because the Plan Participants need these medications to survive, and the Manufacturer Defendants make virtually all diabetes

[177] Senate Insulin Report at 40.

medications available in the United States. The list prices generated by the Defendants' coordinated efforts directly impact out-of-pocket costs at the point of sale.

589. In sum, the entire insulin pricing structure created by the Defendants—from the false prices to the Manufacturers' misrepresentations related to the reasons behind the prices, to the inclusion of the false prices in payor contracts, to the non-transparent Manufacturer Payments, to the misuse of formularies, to the PBMs' representations that they work to lower prices and promote the health of diabetics—is unconscionable, deceptive, and unfair—and it is immensely lucrative for Defendants.

590. Plaintiff did not know, because the Defendants affirmatively concealed, (a) that the Manufacturers and PBMs coordinated to create the PBM formularies in exchange for money and other consideration; (b) that the list prices were falsely inflated; (c) that the list prices were manipulated to satisfy PBM profit demands; (d) that the list prices and net costs (purchase prices) paid by Plaintiff bore no relationship to the fair market value of the drugs themselves or the services rendered by the PBMs in coordinating their pricing; or (e) that the entire insulin pricing structure Defendants created was false.

M. The Insulin Pricing Scheme Has Damaged Plaintiff

591. Plaintiff provides health and pharmacy benefits to its Plan Participants, including employees, retirees, and their dependents.

592. One of the benefits that Plaintiff offers its Plan Participants through its employee health plans is payment of a significant portion of prescription drug purchases.

593. Plaintiff has for years interacted with and/or engaged in business with the PBM Defendants concerning pharmacy services and the at-issue diabetes medications.

594. During various periods of the relevant time, Plaintiff had PBM service agreements in place with Express Scripts, OptumRx and CVS Caremark.

595. During the relevant time period, Plaintiff was unaware of the Insulin Pricing Scheme.

596. Plaintiff relied on Defendants' statements and material omissions made in furtherance of the Insulin Pricing Scheme.

597. Plaintiff relied on Defendants' misrepresentations in paying for the at-issue diabetes medications at prices that would have been lower but for the Insulin Pricing Scheme.

598. Since 2003, the City of Alexandria has spent a significant amount of money on the at-issue diabetes medications.

599. Express Scripts, OptumRx, and CVS Caremark all failed to adhere to principles of good faith and fair dealing in carrying out their respective PBM contracts with Plaintiff. Their respective relationships with Plaintiff were inherently unbalanced and their contracts adhesive. Both Defendants had superior bargaining power and superior knowledge of their relationships with the Manufacturer Defendants, including those that ultimately dictate the drug costs Plaintiff incurred. Although Defendants were supplying a vital service of a quasi-public nature, they both exploited their superior positions to mislead Plaintiff and thwart its expectations, all at great expense to Plaintiff.

600. The Defendants' misrepresentations, omissions, and misconduct—including and as manifested in the Insulin Pricing Scheme—directly and proximately caused economic damage to Plaintiff as a payor/purchaser of Defendants' at-issue diabetes medications.

601. A substantial proportion of the money Plaintiff spent on diabetes medications is attributable to Defendants' inflated prices, which did not arise from competitive market forces but, instead, are directly attributable to the Insulin Pricing Scheme.

602. Because of Defendants' success in concealing the Insulin Pricing Scheme through act and omission, no payor, including Plaintiff, knew, should have known, or could have known during the relevant period that the prices for the at-

issue diabetes medications were (and remain) artificially inflated due to the Insulin Pricing Scheme.

603. As a result, despite receiving some rebates and incurring drug costs based on discounts off list prices, Plaintiff has unknowingly overpaid for the Manufacturer Defendants' diabetes medications, which would have cost less but for the Insulin Pricing Scheme.

604. In addition, because of the inflated AWPs of insulin caused by the Insulin Pricing Scheme, Plaintiff's Plan Participants had greater out-of-pocket expenses (because their co-pays are tied to AWP). As a result, those Plan Participants reached their annual spending caps sooner, such that Plaintiff was obligated to pay more for those Plan Participants to cover the remainder of the plan year.

605. In short, the Insulin Pricing Scheme has directly and proximately caused Plaintiff to substantially overpay for diabetes medications.

606. Because Defendants continue to generate exorbitant, unfair, and deceptive prices for the at-issue drugs through the Insulin Pricing Scheme, the harm to Plaintiff is ongoing.

N. Defendants' Recent Efforts in Response to Rising Insulin Prices

607. In reaction to mounting political and public outcry, Defendants have taken action both on Capitol Hill and in the public relations space to protect and further the Insulin Pricing Scheme.

608. First, in response to public criticism, Defendants have increased their spending to spread their influence in Washington D.C.

609. For example, in recent years Novo Nordisk's political action committee ("PAC") has doubled its spending on federal campaign donations and lobbying efforts. In 2017 alone, Novo Nordisk spent $3.2 million lobbying Congress and federal agencies, its biggest ever investment in directly influencing U.S. policymakers. Eli Lilly and Sanofi also have contributed millions of dollars through their PACs in recent years.

610. Second, Defendants have recently begun publicizing programs ostensibly aimed at lowering the cost of insulins.

611. These affordability measures fail to address the structural issues that caused the price hikes. Rather, these are public relations measures that do not solve the problem.

612. For example, in March 2019, Defendant Eli Lilly announced that it would produce an authorized generic version of Humalog, "Insulin Lispro," and

promised that it would "work quickly with supply chain partners to make [the authorized generic] available in pharmacies as quickly as possible."

613. At the time, Eli Lilly told the Senate Finance Committee that "we can provide a lower-priced insulin more quickly without disrupting access to branded Humalog, which thousands of insured patients depend on, and which will remain available for people who want to continue accessing it through their current insurance plans."[178]

614. When it launched Lispro, its press release said the drug was the "same molecule" as Humalog yet would be sold at half the price of Humalog. Eli Lilly expressly said it was to help make insulin medications "more affordable."[179]

615. What Eli Lilly failed to tell the Committee and the public was that its rebate deals with the PBMs incentivized them to exclude Lispro from their formularies. For example, even though Lispro at $137.50 would be available at half

[178] Joseph B. Kelly Letter to Senate Finance Committee, March 8, 2019.

[179] March 4, 2019, Press Release, *Lilly to Introduce Lower-Priced Insulin*, Eli Lilly and Company available at https://investor.lilly.com/node/40881/pdf (accessed Jan 20, 2022).

the price of Humalog, which remained on-formulary, Express Scripts' exclusion list for 2019[180] specifically blocked it from its formulary.[181]

616. Likewise, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies. Following these news reports, the staff of the Offices of U.S. Senators Elizabeth Warren and Richard Blumenthal prepared a report examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.[182]

617. Eli Lilly did lower the price of Lispro by 40% effective January 1, 2022; but as of January 2023, Lispro does not appear on CVS Caremark's formulary and Humalog was removed. The January 2023 formularies for Express Scripts and OptumRx expressly exclude Lispro.

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[180] *See* Express Scripts 2019 National Preferred Formulary Exclusions, https://www.express-scripts.com/art/pdf/Preferred_Drug_List_ Exclusions2019.pdf

[181] Todd Boudreaux, *Express Scripts Won't Cover Lilly's Generic Insulin*, https://forum.tudiabetes.org/t/express-scripts-won-t-cover-lilly-s-generic-insulin/77581 (last visited July 21, 2023).

[182] Sen. Elizabeth Warren & Sen. Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, (Dec. 2019), https://www.warren.senate.gov/imo/media/doc/Inaccessible%20Insulin%20report.pdf (last visited July 3, 2023).

618. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics' regular insulins and should only be used in an emergency or when traveling. In particular, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous. In any event, ReliOn is not included in any of the PBM Defendants' formularies as of January 2023.

619. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem and the PBMs continue to exclude drugs with lower list prices despite their assurances of cost-savings for payors and their plan participants.

V. TOLLING OF THE STATUTES OF LIMITATIONS

620. Plaintiff has diligently pursued and investigated the claims asserted in this Complaint. Through no fault of its own, Plaintiff did not learn, and could not have learned, the factual bases for its claims or the injuries suffered therefrom until recently. Consequently, the following tolling doctrines apply.

A. Fraudulent Concealment

621. Plaintiff's claims are subject to equitable tolling, stemming from Defendants' knowing and fraudulent concealment of the facts alleged herein. Through the acts, omissions, and misrepresentations alleged throughout this

Complaint, Defendants fraudulently concealed their unfair and deceptive acts or practices.

622. Defendants cannot rely upon any statute of limitations defense, to the extent one would apply, because they undertook efforts to purposefully conceal the Insulin Pricing Scheme, their generation of false list prices, and the fact that the prices for the at-issue diabetes medications were artificially inflated. The Defendants deliberately concealed their behavior and active role in the Insulin Pricing Scheme and other unlawful conduct.

623. Defendants' acts, omissions, and misrepresentations were calculated to lull and induce payors into forbearing legal action or any inquiry that might lead to legal action. Defendants' acts, omissions, and representations were intended to and in fact did prevent Plaintiff from discovering Defendants' unlawful behavior, which is the basis of Plaintiff's claims.

624. Defendants knowingly and fraudulently concealed the facts alleged herein. Defendants knew of the wrongful acts set forth above, and had information pertinent to their discovery, and concealed them from the public, including Plaintiff. As a result of Defendants' conduct, Plaintiff did not know, and could not have known through the exercise of reasonable diligence, of the existence or scope of the Insulin Pricing Scheme or its causes of action.

625. Defendants continually and secretly engaged in the Insulin Pricing

Scheme. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

626. As alleged herein, Defendants affirmatively concealed: (a) that the Manufacturers and PBMs coordinated to create the PBM formularies in exchange for money and other consideration; (b) that the list prices were falsely inflated and manipulated; (c) that the list prices and net costs (purchase prices) paid by payors and patients bore no relationship to the fair market value of the drugs themselves or the services rendered by the PBMs in coordinating their pricing; (d) that the at-issue insulin drugs were selected for inclusion or preferred status on the formularies based on higher prices (and greater potential revenues for Defendants) rather than because of cost-effectiveness or because they were beneficial to payors' plan participants; (e) the exchange of various payments and pricing agreements between the Manufacturers and PBMs; or (f) that the entire insulin pricing structure Defendants created was false.

627. As alleged more fully herein, the PBM Defendants have blocked drug pricing transparency efforts.

628. As alleged more fully herein, the Manufacturer Defendants testified to Congress that they were not responsible for skyrocketing insulin prices, claiming

that they had no control over the pricing, blaming the PBM Defendants for the high prices, and suggesting that they have not profited from astronomical insulin prices.

629. Meanwhile, the PBM Defendants testified to Congress that the Manufacturer Defendants were solely responsible for the list price increases and that the payments that the PBMs receive from the Manufacturer Defendants are unrelated to rising insulin prices.

630. As alleged herein, PBM Defendants concealed the Insulin Pricing Scheme through vague and manipulable definitions of terms in their contracts, including by hiding the fees that the Manufacturer Defendants paid to the PBM Defendants and which the PBM Defendants retained and did not pass along to payors as Rebates.

631. The PBM Defendants also concealed payments they received from the Manufacturer Defendants through their affiliated rebate aggregators, hiding them in complex contractual relationships—often with other Defendants—and not reporting them on their quarterly SEC filings.

632. Defendants coordinated to affirmatively withhold the truth about the Insulin Pricing Scheme from payors, patients, and the public and concealed the falsity of representations made to payors by closely guarding their pricing negotiations, structures, agreements, sales figures, and the flow of money and other consideration between them.

633. Plaintiff did not know, and could not reasonably have discovered, the full extent of agreements between the PBM Defendants and the Manufacturer Defendants or payments the Manufacturer Defendants made to the PBMs because Defendants actively concealed these agreements and payments.

634. Despite the claims of transparency made to payors and to the public, Defendants have never revealed the full amount of drug-specific payments they have exchanged or received. Plaintiff reasonably relied on Defendants' claims of transparency.

635. Defendants intended that their actions and omissions would be relied upon by payors like Plaintiff. Plaintiff did not know, and did not have the means to know, the truth due to Defendants' actions and omissions.

636. Plaintiff reasonably relied on Defendants' affirmative statements to Congress and the public, and in contracts between PBMs and their clients, that Defendants were working to lower insulin prices and provide payors with cost savings.

637. Even today, Defendants' efforts to conceal the pricing of diabetes medications and the arrangements, relationships, and agreements between and among the Manufacturer Defendants and the PBM Defendants, i.e., the Insulin Pricing Scheme, continue to obscure Defendants' unlawful conduct from Plaintiff and the general public.

638. The purposes of the statute of limitations are satisfied because Defendants cannot claim any prejudice due to an alleged late filing where Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

639. In light of the information set forth above, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

640. Any applicable statutes of limitations therefore have been tolled.

B. Continuing Violations

641. The acts, omissions, and misrepresentations alleged throughout this Complaint have continued to the present day. Defendants' systematic misconduct constitutes a continuous, unbroken violation of the law that has caused, and continues to cause, continuous economic harm to Plaintiff.

642. Accordingly, all applicable statutes of limitations are tolled.

VI. CLAIMS FOR RELIEF

COUNT ONE

Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") – 18 U.S.C. § 1962(c) (Against All Defendants)

643. Plaintiff re-alleges and incorporates by reference all preceding and succeeding factual allegations.

644. Plaintiff brings this count against all Defendants for violations of 18 U.S.C. § 1962(c).

645. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts and OptumRx are (a) culpable "persons" who (b) willfully and knowingly (c) committed and conspired to commit two or more acts of mail and wire fraud (d) through a "pattern" of racketeering activity that (e) involves an "association in fact" enterprise, (f) the results of which had an effect on interstate commerce.

A. Defendants Are Culpable "Persons" Under RICO

646. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx, separately, are "persons" as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

647. Each one of Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx are separate entities and "persons" that are distinct from the RICO enterprises alleged below.

B. The Manufacturer–PBM RICO Enterprises

648. For the purposes of this claim, the RICO enterprises are six separate associations-in-fact consisting of one of each of the PBM Defendants and one of each of the Manufacturer Defendants, including those entities' directors, employees, and agents: the Eli Lilly-CVS Caremark Enterprise; the Eli Lilly-OptumRx Enterprise; the Eli Lilly-Express Scripts Enterprise; the Novo Nordisk-CVS

Caremark Enterprise; the Novo Nordisk-OptumRx Enterprise; the Novo Nordisk-Express Scripts Enterprise; the Sanofi-CVS Caremark Enterprise; the Sanofi-OptumRx Enterprise; and the Sanofi-Express Scripts Enterprise.

649. These association-in-fact enterprises are collectively referred to herein as the "Manufacturer–PBM Enterprises."

650. Each Manufacturer–PBM Enterprise is a separate, ongoing, and continuing business organization consisting of corporations and individuals associated for the common purpose of manufacturing, selling, and facilitating the purchase of the Manufacturer Defendants' products, including the at-issue drugs. For example:

a. The Eli Lilly–OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

b. The Eli Lilly–Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog

medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

c. The Eli Lilly-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

d. The Novo Nordisk–OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

e. The Novo Nordisk–Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N,

Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

f. The Novo Nordisk-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

g. The Sanofi–OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

h. The Sanofi–Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

i. The Sanofi–CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua.

651. Each Manufacturer–PBM Enterprise engaged in the shared purpose of exchanging false list prices and secret Manufacturer Payments for preferred formulary positions for the at-issue drugs in order to control the market for diabetes medications and profit off diabetics and payors, including the Plaintiff.

652. The members of each enterprise are bound by contractual relationships, financial ties, and the ongoing coordination of activities.

653. There also is a common communication network by which Eli Lilly and OptumRx, Eli Lilly and Express Scripts, Eli Lilly and CVS Caremark, Novo Nordisk and OptumRx, Novo Nordisk and Express Scripts, Novo Nordisk and CVS Caremark, Sanofi and OptumRx, Sanofi and Express Scripts, and Sanofi and CVS Caremark share information and meet on a regular basis. These communications include, but are not limited to, communications relating to the use of false list prices for the at-issue diabetes medications and the regular flow of Manufacturer Payments from each Manufacturer Defendant to each PBM Defendant in exchange for formulary placement.

654. Each Manufacturer–PBM Enterprise functions as continuing but separate unit separate and apart from the pattern of racketeering activity in which it engages. Each Manufacturer–PBM Enterprise, for example, engages in the manufacture, distribution and sale of medications and other products other than the at-issue insulin and insulin-analog medications. Additionally, each Manufacturer engages in conduct other than mail fraud and wire fraud in furtherance of the Insulin Pricing Scheme.

655. At all relevant times, each of the Manufacturer–PBM Enterprises was operated and conducted for unlawful purposes by each Manufacturer Defendant and PBM Defendant, namely, carrying out the Insulin Pricing Scheme.

656. Each Manufacturer–PBM Enterprise derived secret profits from these activities that were greater than those any one of the Manufacturer Defendants or PBM Defendants could obtain absent their misrepresentations regarding their pricing schemes.

657. The Manufacturer-PBM Enterprises resulted in benefits for the Defendants that could not have been achieved absent the enterprises. For example, the Manufacturer Defendants achieved formulary access without real price reductions by raising list prices and paying kickbacks to the PBM Defendants. The PBM Defendants likewise could not have obtained inflated rebates, administrative fees, and other payments without colluding with the Manufacturers to raise list

prices. In other words, each Manufacturer-PBM Enterprise engaged in a scheme to corrupt the insulin market by artificially inflating list prices in exchange for preferred formulary placement.

658. To accomplish this common purpose, each Manufacturer Defendant periodically and systematically inflated the prices of the at-issue drugs and then secretly paid a significant, yet undisclosed, portion of this inflated price back to the PBM Defendants in the form of Manufacturer Payments.

659. Each Manufacturer–PBM Enterprise did so willfully and with knowledge that Plaintiff paid for the at-issue drugs at prices directly based on the false list prices.

660. Each Manufacturer–PBM Enterprise's inflation of the list prices and secret Manufacturer Payments was a quid pro quo exchange for preferred formulary placement.

661. Each Manufacturer–PBM Enterprise concealed from Plaintiff that these false prices and secret Manufacturer Payments resulted in each Manufacturer gaining formulary access without requiring significant price reductions and resulted in higher profits for each PBM Defendant, whose earnings increase the more inflated the price is and the more payment it receives from each Manufacturer Defendant.

662. Each Manufacturer–PBM Enterprise also shares a common purpose of perpetuating the use of the false list prices for the at-issue drugs as the basis for the price that payors, including the Plaintiff, and diabetics pay for diabetes medications.

663. The Manufacturer Defendants would not be able to offer large pricing spreads to the PBM Defendants in exchange for favorable formulary positions without the use of the false list prices as the basis for the price paid by diabetics and payors, including the Plaintiff, for the at-issue drugs.

664. The PBM Defendants share this common purpose because nearly all the revenue and profit generated from the at-issue drugs is tied to the false inflated prices generated by the Insulin Pricing Scheme. Without diabetics and payors, including the Plaintiff, paying for diabetes medications based on the inflated list prices, their profits from the Insulin Pricing Scheme would decrease.

665. As a result, the PBM Defendants have, with the knowing and willful participation and assistance of each Manufacturer Defendant, engaged in hidden profit-making schemes falling into four general categories: (a) garnering undisclosed Manufacturer Payments from each Manufacturer Defendant that the PBM Defendants retain to a large extent; (b) generating substantial profits from pharmacies because of the falsely inflated prices; (c) generating profits on the diabetes medications sold through the PBM Defendants' own mail-order and retail

pharmacies; and (d) keeping secret discounts each Manufacturer Defendant provides in association with the PBM Defendants' mail-order and retail operations.

666. At all relevant times, each PBM Defendant and each Manufacturer Defendant have been aware of their respective Manufacturer–PBM Enterprise's conduct, have been knowing and willing participants in and coordinator of that conduct and have reaped profits from that conduct.

667. None of the PBM Defendants or the Manufacturer Defendants alone could have accomplished the purposes of the Manufacturer–PBM Enterprises without the other entities.

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme

668. Each Manufacturer–PBM Enterprise knowingly made material misrepresentations to the public and the Plaintiff in furtherance of the Insulin Pricing Scheme, including publishing artificially inflated prices for insulin on published indices and representing that:

a. the false list prices for the at-issue diabetes medications were reasonably related to the actual prices realized by Defendants and were a reasonable and fair basis on which to base the price Plaintiff paid for these drugs;

b. each Manufacturer priced its at-issue drugs according to each drug's value to the healthcare system and the need to fund innovation;

c. the Manufacturer Payments paid back to each PBM Defendant for each at-issue drug were for Plaintiff's benefit;

d. all "rebates" and discounts negotiated by the PBM Defendants with the Manufacturer Defendants were remitted to Plaintiff;

e. the "rebates" negotiated by the members of each enterprise saved Plaintiff money;

f. each Manufacturer Defendant and each PBM Defendant were transparent with Plaintiff regarding the Manufacturer Payments and the PBMs did not retain any funds associated prescription drug rebates or the margin between guaranteed reimbursement rates and the actual amount paid to the pharmacies; and

g. the PBM Defendants constructed formularies in a manner that lowered the price of the at-issue drugs and promoted the health and safety of diabetics.

669. Each false list price published by the Manufacturer Defendants constituted a material misrepresentation to Plaintiff and the public, in that each purported to be a fair market price for an at-issue drug, and each omitted to disclose the fraudulent spread between the list price and the net price of the medication or the basis therefor. Examples of other affirmative representations by each RICO

Defendant in furtherance of each enterprise's Insulin Pricing scheme are set forth herein.

670. At all times relevant to this Complaint, each Manufacturer–PBM Enterprise knew the above-described representations to be false.

671. At all times relevant to this Complaint, each Manufacturer–PBM Enterprise intentionally made these representations for the purpose of inducing Plaintiff into paying artificially inflated prices for diabetes medications.

672. Plaintiff relied on the material misrepresentations and omissions made by each Manufacturer–PBM Enterprise in paying prices for the at-issue diabetes medications based upon the false prices generated by Insulin Pricing Scheme.

673. Additionally, each PBM–Manufacturer Enterprise relied on the list prices negotiated and published by the other PBM–Manufacturer enterprises in setting their own list prices and determining the value of the kickbacks paid to the PBMs. Plaintiff was injured by the inflated prices that arose as a result.

674. Express Scripts, OptumRx, and CVS Caremark convinced Plaintiff to pay prices for the at-issue drugs based on the false list price by utilizing the misrepresentations listed above to convince Plaintiff that they had secured lower prices when, in fact, they did the opposite, all while concealing the Insulin Pricing Scheme.

675. Without these misrepresentations and each RICO Defendant's failure to disclose the Insulin Pricing Scheme, each Manufacturer–PBM Enterprise could not have achieved its common purpose, as Plaintiff would not have been willing to pay these false list prices.

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

676. Each of the Manufacturer–PBM Enterprises engaged in and affected interstate commerce because each engaged in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order and retail pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

677. Each Manufacturer–PBM Enterprise participated in the administration of diabetes medications to millions of individuals located in all 50 states, including in this District.

678. Each Manufacturer Defendant's and each PBM Defendant's illegal conduct and wrongful practices were carried out by an array of employees, working

across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

679. The nature and pervasiveness of the Insulin Pricing Scheme, which included each Manufacturer Defendant's and each PBM Defendant's corporate headquarters operations, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other and with pharmacies, physicians, payors, and diabetics throughout the United States.

680. Each Manufacturer–PBM Enterprise's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including:

a. marketing materials about the published prices for diabetes medications, which each Manufacturer Defendant sent to each PBM Defendant across the country, in the City of Alexandria, and throughout Virginia;

b. written and oral representations of the false list prices of diabetes medications that each Manufacturer Defendant and each PBM Defendant made at least annually and, in many cases, several times during a single year to the public;

c. thousands of written and oral communications discussing, negotiating, and confirming the placement of each Manufacturer Defendant's diabetes medications on each PBM Defendant's formularies;

d. written and oral representations made by each Manufacturer Defendant regarding information or incentives paid back to each PBM Defendant for each diabetes medications sold and/or to conceal these incentives or the Insulin Pricing Scheme;

e. written communications made by each Manufacturer Defendant, including checks, relating to Manufacturer Payments paid to each PBM Defendant to persuade them to advocate the at-issue diabetes medications;

f. written and oral communications with U.S. government agencies that misrepresented what the published prices were or that were intended to deter investigations into the true nature of the published prices or to forestall changes to reimbursement based on something other than published prices;

g. written and oral communications with payors, including the Plaintiff, regarding the price of diabetes medications;

h. written and oral communications to the Plaintiff, including marketing and solicitation material sent by each PBM Defendant regarding the

existence, amount, or purpose of payments made by each Manufacturer Defendant to each PBM Defendant for the diabetes medications described herein and the purpose of each PBM Defendant's formularies;

i. transmission of published prices to third parties and payors, including the Plaintiff; and

j. receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of the Insulin Pricing Scheme.

681. Although Plaintiff pleads the dates of certain communications in allegations incorporated into this Count, it cannot allege the precise dates of others without access to books and records within each RICO Defendant's exclusive custody and control. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, and each Manufacturer Defendant and PBM Defendant took deliberate steps to conceal its wrongdoing.

E. Conduct of the Manufacturer–PBM Enterprises' Affairs

682. Each Manufacturer Defendant and PBM Defendant participates in the operation and management of Manufacturer–PBM Enterprises with which it is associated and, in violation of Section 1962(c) of RICO, and conducts or participates in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation is carried out in the following ways:

a. Each Manufacturer Defendant directly controls the secret Manufacturer Payments it provides to each PBM Defendant for its diabetes medications.

b. The PBM Defendants directly manage and control their respective drug formularies and the placement of the at-issue diabetes medications on those formularies.

c. The PBM Defendants intentionally select higher-priced diabetes medications for formulary placement and exclude lower priced ones in order to generate larger profits and they coordinate with the Manufacturer Defendants to increase the availability and use of higher-priced medications because they are more profitable for both groups of Defendants.

d. Each Manufacturer Defendant directly controls the publication of the false list prices generated by the Insulin Pricing Scheme.

e. Each Manufacturer Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform each PBM Defendant of the profit potential from its diabetes medications.

f. Each PBM Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform payors and the public

of the benefits and cost-saving potential of each PBM Defendant's formularies and negotiations with the Manufacturers.

g. Each PBM Defendant directs and controls each enterprise's direct relationships with payors such as the Plaintiff by negotiating the terms of and executing the contracts that govern those relationships.

h. Each PBM Defendant directs and controls each enterprise's Insulin Pricing Scheme by hiding, obfuscating, and laundering Manufacturer Payments through their affiliated entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.

i. Each PBM Defendant distributes through the U.S. mail and interstate wire facilities, promotional and other materials that claim the Manufacturer Payments paid from each Manufacturer Defendant to each PBM Defendant save Plaintiff and other payors money on the at-issue drugs.

j. Each Manufacturer Defendant represented to the Plaintiff—by publishing and promoting false list prices without stating that these published prices differed substantially from the prices realized by each Manufacturer Defendant and each PBM Defendant—that the published prices of diabetes medications reflected or approximated the actual price

realized by Defendants and resulted from transparent and competitive, fair market forces.

F. Defendants' Pattern of Racketeering Activity

683. Each Manufacturer Defendant and each PBM Defendant have conducted and participated in the affairs of their respective Manufacturer–PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

684. Each Manufacturer Defendant's and each PBM Defendant's pattern of racketeering involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which each Manufacturer Defendant and each PBM Defendant intended to defraud Plaintiff.

685. By intentionally and falsely inflating the list prices, by misrepresenting the purpose behind both the Manufacturer Payments made from each Manufacturer Defendant to each PBM Defendant and each PBM Defendant's formulary construction, and by subsequently failing to disclose such practices to Plaintiff, each

Manufacturer Defendant and each PBM Defendant engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

686. Each Manufacturer Defendant's and each PBM Defendant's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff.

687. Each separate use of the U.S. mails and/or interstate wire facilities employed by each Manufacturer Defendant and each PBM Defendant was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff.

688. Each Manufacturer Defendant and each PBM Defendant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer–PBM Enterprises with which each of them is and was associated in fact.

G. The RICO Defendants' Motive

689. Each Manufacturer Defendant's and each PBM Defendant's motive in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Manufacturer–PBM Enterprises described herein was to control the market for diabetes medications and falsely obtain sales of and profits from diabetes medications.

690. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors like Plaintiff, to advocate the use of each Manufacturer Defendant's products and to pay for those diabetes medications based on a falsely inflated price. Each Manufacturer Defendant used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profits. Each PBM Defendant used the Insulin Pricing Scheme to falsely inflate the price payors like Plaintiff paid for diabetes medications in order to profit off the Insulin Pricing Scheme, as discussed above.

H. The Manufacturer–PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff

691. Each Manufacturer–PBM Enterprise's violations of federal law and pattern of racketeering activity have directly and proximately caused the Plaintiff to be injured in its business or property.

692. The prices Plaintiff pays for the at-issue drugs are tied directly to the false list prices generated by the Insulin Pricing Scheme.

693. No other intermediary in the supply chain has control over or is responsible for the list prices on which nearly all Plaintiff's payments are based other than the Manufacturer–PBM Defendant Enterprises.

694. Defendants collectively set the prices that the Plaintiff paid for the at-issue diabetes medications.

695. During the relevant period, Express Scripts, OptumRx, and CVS Caremark provided PBM services to Plaintiff at various times, from which the PBM Defendants benefitted.

696. During the relevant period, Plaintiff paid Express Scripts, OptumRx, and CVS Caremark for the at-issue drugs.

697. Each Manufacturer–PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the false list prices upon which the price Plaintiff paid was based.

698. Thus, Plaintiff was damaged by reason of the Insulin Pricing Scheme. But for the misrepresentations and false prices created by the Insulin Pricing Scheme that each Manufacturer–PBM Enterprise employed, Plaintiff would have paid less for diabetes medications.

699. Because the Insulin Pricing Scheme resulted in payors and consumers paying supracompetitive prices for the at-issue medications, the scheme could not have continued without each Manufacturer-PBM Enterprise's participation. In other words, if one of the Manufacturer-PBM Enterprises had opted not to participate in the scheme—and not inflated its list prices—the other enterprises could not have continued to overcharge their own clients. Each enterprise's participation in the scheme—and execution of its own pattern of racketeering activity—was essential to the overall scheme's survival and a direct cause of Plaintiff's injuries.

700. While Defendants' scheme injured an enormous number of payors and plan members, Plaintiff's damages are separate and distinct from those of any other victim that was harmed by the Manufacturer–PBM Defendant Enterprises' Insulin Pricing Scheme.

701. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to the Plaintiff for three times the damages that were sustained, plus the costs of bringing this action, including reasonable attorneys' fees.

702. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, the Plaintiff seeks injunctive relief against each Manufacturer Defendant and each PBM Defendant for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/or conceal and suppress material facts concerning their false and inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees.

703. Absent an injunction, the effects of this fraudulent, unfair, and unconscionable conduct will continue. The Plaintiff continues to purchase the at-issue diabetes medications. The Plaintiff will continue to pay based on the Defendants' false list prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. The Plaintiff

seeks injunctive relief, including an injunction against each Manufacturer and each PBM Defendant, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their conduct in furtherance of the Insulin Pricing Scheme.

COUNT TWO

Violations of RICO, 18 U.S.C. § 1962(d) By Conspiring to Violate 18 U.S.C. § 1962(c) (Against All Defendants)

704. Plaintiff re-alleges and incorporates by reference all preceding and succeeding factual allegations.

705. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

706. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in the Insulin Pricing Scheme.

707. As set forth in detail above, as well as in the Civil Conspiracy count below, Defendants each knowingly agreed to facilitate the Insulin Pricing Scheme and each has engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. Specifically, Defendants agreed to and did inflate the prices of the at-issue drugs in lockstep to achieve an unlawful purpose;

Defendants agreed to and did make false or misleading statements or material omissions regarding the reasons for these price increases, the purpose of the Manufacturer Payments exchanged between Defendants and the PBMs' formulary construction; and PBMs agreed to and did, in concert, request and receive larger Manufacturer Payments and higher prices in exchange for formulary placement.

708. The nature of the above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

709. Defendants have engaged and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. multiple instances of mail fraud in violations of 18 U.S.C. § 1341;

b. multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and

c. multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

710. Defendants' conspiracy to violate the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff has been injured in its property by reason of these violations: Plaintiff has paid more for the at-issue drugs than it would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

711. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiff for three times the damages the City has sustained, plus the cost of this action, including reasonable attorneys' fees.

COUNT THREE

Virginia Consumer Protection Act
Va. Code Ann. § 59.1-196 *et seq.*
(Against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, OptumRx, and CVS Caremark)

712. Plaintiff re-alleges and incorporates by reference all preceding and succeeding factual allegations.

713. Plaintiff brings this claim against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, OptumRx, and CVS Caremark. All are referred to collectively throughout Count Three as "Defendants." Eli Lilly, Novo Nordisk and Sanofi are referred to throughout Count Three as "Manufacturer Defendants." Express Scripts, OptumRx, and CVS Caremark are referred to throughout Count Three as "PBM Defendants."

714. The Virginia Consumer Protection Act (VCPA) is "remedial legislation to promote fair and ethical standards of dealings between suppliers and the consuming public." Va. Code Ann. § 59.1-197.

715. The VCPA prohibits certain "fraudulent acts or transactions by a supplier in connection with a consumer transaction." Va. Code Ann. § 59.1-200(A).

716. The VCPA proscribes a broad range of fraudulent or deceptive conduct by suppliers in consumer transactions that is not limited to common-law fraud.

717. Defendants are "suppliers" within the meaning of, and subject to, the provisions of the VCPA, Va. Code Ann. § 59.1-198.

718. Defendants' fraudulent acts or practices, as alleged herein, were committed in connection with "consumer transactions," as defined by Va. Code Ann. § 59.1-198, because they occurred in connection with "[t]he advertisement, sale, lease, license or offering for sale, lease or license, of goods or services to be used primarily for personal, family or household purposes." The at-issue insulin drugs sold, or offered for sale, by Manufacturer Defendants and PBM Defendants to Plaintiff and other consumers are "goods" that are used primarily for personal or family healthcare. Similarly, the PBM Defendants' services—managing pharmacy benefits for Plaintiff's Plan Participants—are services primarily for personal or family healthcare.

719. The VCPA permits "any person who suffers loss as a result of a violation" of the Act to bring an individual action to recover damages. Va. Code Ann. § 59.1-204(A). If the trier of fact finds that the violation is willful, plaintiff may be awarded damages up to three times the amount of actual damages. Id.

720. Any person who suffers loss as a result of a violation of the VCPA may also receive reasonable attorneys' fees and costs. Va. Code Ann. § 59.1-204(B).

721. Plaintiff is a "person" within the meaning of the provisions of the Virginia Consumer Protection Act, Va. Code Ann. § 59.1-198.

722. Plaintiff, as one of several enumerated governmental entities, is also authorized to bring an action to enjoin violations of the VCPA. Va. Code Ann. § 59.1-203(A) (authorizing the Commonwealth, as well as any city, county or town, to bring action for injunctive relief). Authorized governmental entities need not prove damages to obtain injunctive relief. Id.

723. If the Court determines that any of the Defendants has willfully engaged in an act or practice that violates the VCPA, Plaintiff, as an enumerated governmental entity, may also recover a civil penalty up to $2,500 per violation, to be paid to the Literary Fund. Va. Code Ann. § 59.1-206(A). In addition, Plaintiff may also recover any applicable civil penalties, costs, and reasonable expenses incurred in investigating and preparing the case, not to exceed $1,000 per violation, and attorney's fees. Va. Code Ann. § 59.1-206(D).

724. The Court may order additional relief as "necessary to restore to any identifiable person any money or property . . . which may have been acquired from such person" by means of practices found to be unlawful under § 59.1-200. Va. Code Ann. § 59.1-205.

725. Defendants' misconduct as described throughout this Complaint, collectively and as individuals, constitutes "fraudulent acts or practices," as defined in Va. Code Ann. § 59.1-200, and was therefore unlawful.

726. Defendants are independently liable for their own misconduct in violation of the VCPA and are liable for their collective efforts in furtherance of the Insulin Pricing Scheme. Using a complex structure of interdependent entities, Defendants confused and misled consumers about each Defendant's respective role in an attempt to evade liability for the fraudulent scheme as a whole, and for the acts and omissions of the enterprise's interdependent participants.

727. By jointly carrying out and concealing the Insulin Pricing Scheme, as described herein, Defendants violated the VCPA, Va. Code Ann. § 59.1-200, by, at a minimum, committing the following fraudulent acts or practices:

a. misrepresenting that goods or services have certain characteristics or benefits, Va. Code Ann. § 59.1-200(A)(5);

b. making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions, Va. Code Ann. § 59.1-200(A)(9); and

c. using any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction, Va. Code Ann. § 59.1-200(A)(14).

728. Defendants' misconduct in violation of the VCPA includes the creation and implementation of the Insulin Pricing Scheme, which included:

a. The Manufacturer Defendants published prices for the at-issue drugs and, in doing so, held these prices out as the actual prices for these drugs despite knowing these prices were artificially inflated and untethered from the cost of the drugs or the price the Manufacturers were paid for them—all with the PBM Defendants' knowledge, consent, and cooperation.

b. The Manufacturer Defendants misrepresented and actively concealed the true reasons why they set and raised list prices—the truth being that it was to increase revenues and profits and to offer higher prices and larger Manufacturer Payments to the PBMs—all with the PBM Defendants' knowledge, consent, and cooperation.

c. The PBM Defendants furthered the scheme by using the artificially inflated list prices to determine the inflated prices paid by payors, including Plaintiff and Plaintiff's Plan Participants—all with the Manufacturer Defendants' knowledge, consent, and cooperation.

d. The PBM Defendants represented to payors, including Plaintiff, and to the public that they worked to generate savings with respect to the at-issue drugs and to promote the health of diabetics. Instead, directly

counter to their representations, the PBMs drove up the prices of the at-issue drugs and damaged payors, including Plaintiff, by demanding ever-increasing Manufacturer Payments that, in turn, increased what otherwise would have been the retail prices for the at-issue drugs—all with the Manufacturer Defendants' knowledge, consent, and cooperation.

e. The PBM Defendants have hidden, obfuscated, and laundered these Manufacturer Payments through their affiliated entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.

f. The PBM Defendants intentionally selected higher-priced diabetes medications for formulary placement and excluded lower priced ones in order to generate larger profits and coordinated with the Manufacturer Defendants to increase the availability and use of higher priced medications because they are more profitable for both groups of Defendants.

g. The PBM Defendants misled their payors, including Plaintiff, as to the true nature of value of the services they provided and reaped illicit profits exponentially greater than the fair market value of the services they

purported to provide—all with the Manufacturer Defendants' knowledge, consent, and cooperation.

h. The PBM Defendants owed a duty to disclose the true facts to their payor clients, including Plaintiff, but intentionally chose instead to conceal them, both to further the Insulin Pricing Scheme and to conceal it from payors, including Plaintiff—all with the Manufacturer Defendants' knowledge, consent, and cooperation.

729. In addition, Defendants engaged in a variety of fraudulent acts or practices specifically with regard to the prices of the at-issue drugs, all of which violated the VCPA. Those fraudulent acts or practices include, but are not limited to, the following:

a. A characteristic of every commodity in Virginia's economy is its price, which is represented by every seller to every buyer that the product being sold is being sold at a legal, competitive, and fair market value.

b. The Manufacturer Defendants reported and published artificially inflated list prices for each at-issue drug and, in doing so, represented that the reported prices were reasonably related to the net prices for the at-issue drugs and otherwise reflected the fair market value for the drugs—all with the PBM Defendants' knowledge, consent, and cooperation.

c. The PBM Defendants misrepresented to payors and the public that their formularies and the portion of the Manufacturer Payments they disclosed have the characteristic and benefit of lowering the price of the at-issue drugs and promoting the health of diabetics when, in fact, the opposite is true.

d. The PBM Defendants utilized the artificially inflated price—which they are directly responsible for inflating and which they know is untethered from the actual price—to make false and misleading statements regarding the amount of savings the PBMs generate for payors and the public.

e. Defendants made false and misleading representations of fact that the prices for the at-issue diabetes medications were legal, competitive, and fair market value prices.

f. At no point did the Defendants reveal that the prices for the at-issue drugs were not legal, competitive or at fair market value—rather, they coordinated to overtly mislead the public and payors, including Plaintiff, and undertook a concerted effort to conceal the truth.

g. At no point did these Defendants disclose that the prices associated with the at-issue drugs were generated by the Insulin Pricing Scheme—rather,

they overtly misled the public and payors, including Plaintiff, and undertook a concerted effort to conceal the truth.

h. At least once a year for each year during the relevant period, Defendants reported and published false prices for each at-issue drug and in doing so represented that the list prices were the actual, legal and fair prices for these drugs and resulted from competitive market forces when they knew that was not true.

i. In addition, by granting the at-issue drugs preferred formulary position—formulary positions that the PBMs represent are reserved for reasonably priced drugs and that are meant to promote cost savings and the health of diabetics—the PBM Defendants knowingly and purposefully utilized the false prices that were generated by the Insulin Pricing Scheme—all with the Manufacturer Defendants knowledge, consent, and cooperation.

j. By granting the at-issue diabetes medications preferred formulary positions, the PBM Defendants ensured that prices generated by the Insulin Pricing Scheme would harm Plaintiff—all with the Manufacturer Defendants knowledge, consent, and cooperation.

k. The PBM Defendants also misrepresented their formularies promoted the cost-savings to Plaintiff.

l. Defendants' representations are false, and Defendants knew they were false when they were made. Defendants knew that the prices they reported and utilized are artificially inflated for the purpose of maximizing revenues and profits pursuant to the Insulin Pricing Scheme.

m. These Defendants not only knew that the PBMs' formulary construction fueled the precipitous price increases that damaged Plaintiff's financial well-being, but coordinated in ways that made such harm inevitable—all for the sole purpose of generating more revenues and profits for both groups of Defendants.

n. Defendants affirmatively withheld this truth from Plaintiff, even though these Defendants knew that the Plaintiff's intention was to pay the lowest possible price for diabetes medications and expectation was to pay a legal, competitive price that resulted from transparent market forces.

o. Defendants made false and misleading misrepresentations of fact related to the Manufacturer Payments and the negotiations that occurred between the PBM and Manufacturer Defendants.

p. The PBM Defendants knowingly made false and misleading statements concerning the reasons for, existence of, and amount of price reductions by misrepresenting that the Manufacturer Payments lower the overall

price of diabetes medications and reduce payor costs while promoting the health of diabetics.

q. These representations were false, and Defendants knew they were false when they were made. The PBM Defendants knew that the Manufacturer Payments were not reducing the overall price of diabetes medications but rather are an integral part of the secret Insulin Pricing Scheme and are responsible for the inflated prices.

r. The PBM Defendants owed a duty to disclose the true facts to their payor clients, including Plaintiff, but intentionally chose instead to conceal them, both to further the Insulin Pricing Scheme and to conceal it from payors, including Plaintiff—all with the intent of misrepresenting the characteristics and benefits of their services and the existence and nature of purported price reductions they obtained for payors, including Plaintiff. All of this was done with the Manufacturer Defendants' knowledge, consent, and cooperation.

s. Defendants continue to make these misrepresentations and to publish prices generated by the Insulin Pricing scheme, and Plaintiff continues to purchase diabetes medications at inflated prices. Defendants' fraudulent acts and practices, including its misrepresentations, concealments, omissions, and/or suppressions of material facts, had a tendency or

capacity to mislead and create a false impression in payors like Plaintiff, and were likely to, and did in fact, deceive those payors, including Plaintiff.

t. Defendants' conduct, including but not limited to their concealment of information regarding pricing and fee arrangements, which contributed to inflated, fictitious prices, created a likelihood that payors and patients did not understand that the prices they were paying for insulin were artificially inflated prices rather than competitive market prices.

730. Defendants' fraudulent acts and practices were intended to cause and in fact caused confusion and misunderstanding among payors, including Plaintiff.

731. The Manufacturer Defendants and PBM Defendants made these misrepresentations for the sole purpose of inducing reliance by payors, including Plaintiff, into purchasing diabetes medications through PBM Defendants.

732. Defendants knew that the representations described above were false when they made the representations—the rebates and formulary positions agreed upon between Defendants did not lower the price Plaintiff or other payors paid for insulin, but rather were primary factors driving the exponential increase in the amount that Plaintiff, other payors, and patients paid for insulins during the relevant timeframe.

733. Defendants made these false representations directly to Plaintiff and other payors through, among other things, oral and written communications, the inclusion of the reported price in their contracts with payors as a determinant of the price for diabetes medications, marketing materials, presentations, publications of the artificially inflated reported price, and in public statements.

734. Defendants' false representations and omissions were material to Plaintiff and other payors.

735. Plaintiff reasonably relied on Defendants' deception in paying for diabetes medications at inflated prices. Plaintiff had no way of discerning that Defendants were, in fact, deceiving it because Defendants possessed exclusive knowledge regarding the nature of the pricing of diabetes medications; intentionally concealed the foregoing from Plaintiff; and made false, fraudulent, incomplete, or negligent representations about the pricing of the diabetes medications and Defendants' role in that pricing, while purposefully withholding material facts from Plaintiff that contradicted those representations.

736. Defendants' actions, representations, and misrepresentations demonstrate callous disregard for not only the rule of law but also public health, safety, and well-being.

737. As a direct and proximate result of Defendants' fraudulent Insulin Pricing Scheme, Plaintiff sustained damages, including but not limited to paying excessive and inflated prices for diabetes medications described herein.

738. Defendants are liable to Plaintiff for damages in an amount to be proven at trial.

739. Moreover, because Defendants acted knowingly, wantonly, maliciously, recklessly, deliberately, and with intent to defraud Plaintiff, other payors, and patients for the purpose of enriching themselves to the detriment of Plaintiff, other payors, and patients, Defendants' conduct was willful within the meaning of the VCPA. Defendants' fraudulent acts and practices—including their concealment and suppression of material facts—were carried out with the intent that Plaintiff, among others, would rely upon them, which Plaintiff reasonably did, proximately causing actual economic damage to Plaintiff.

740. The acts and practices alleged herein are ongoing, repeated, and affect the public interest.

741. Because the acts alleged herein were willful, this Court should impose on Defendants an appropriate civil penalty for each violation.

742. Plaintiff has reason to believe, based on the facts alleged herein, that Defendants' omissions, misrepresentations, and deceptive practices have violated, and will continue to violate, the VCPA, absent the grant of an injunction.

743. Unless restrained by this Court, Defendants will likely continue to engage in the unlawful practices alleged herein. These ongoing, and likely future, violations by Defendants of the VCPA are contrary to the public interest, thereby necessitating an injunction to restrain and prevent further such misconduct by Defendants.

744. Because individual consumers also paid artificially inflated prices for insulin because of Defendants' Insulin Pricing Scheme, Plaintiff further seeks, by way of restoration, an order directing Defendants to disgorge all money acquired or retained by Defendants as a result of their violations of the VCPA and to use those sums to restore to individual consumers the amounts that those individuals have overpaid for insulin.

745. Accordingly, Plaintiff seeks damages (to include treble damages); injunctive relief; attorneys' fees and costs; civil penalties; restoration; and any other relief to which Plaintiff may be entitled.

746. Although individual actions pursuant to § 59.1-204 of the VCPA are subject to a two-year statute of limitations from the date of injury, enforcement actions filed by authorized government entities, which include Plaintiff, are not subject to the limitations period. Va. Code Ann. § 59.1-204.1.

747. To the extent the two-year statute of limitations is applicable to Plaintiff's individual action for damages, that limitations period was tolled due to

Defendants' fraudulent concealment of the Insulin Pricing Scheme and/or due Defendants' continuing violations of the VCPA.

748. Each at-issue purchase Plaintiff made for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the VCPA.

COUNT FOUR

Common Law Fraud
(Against All Defendants)

749. Plaintiff re-alleges and incorporates by reference all preceding and succeeding factual allegations.

750. CVS Caremark, Express Scripts, OptumRx and the Manufacturer Defendants affirmatively misrepresented, omitted, or concealed and suppressed material facts concerning, among other things:

a. the true cost and price of the at-issue drugs;

b. the inflated and fraudulent nature of the list prices set and charged by Defendants for the at-issue drugs;

c. the existence, amount, flow, and purposes of discounts and rebates offered or negotiated by Defendants for the at-issue medications; and

d. the role that Defendants played in the price paid for the at-issue, including marketing materials and other public statements stating that Defendants decrease the price of prescription drugs for consumers.

751. These Defendants' false representations and omissions were material to Plaintiff.

752. Defendants knew that their representations and omissions were false and misleading. They were aware, for example, that the list prices for the at-issue drugs were excessive, inflated, and untethered to any competitive market price. They understood that these inflated list prices were artificially inflated to fund kickbacks for the PBMs in exchange for preferred formulary placement.

753. These Defendants intended that Plaintiff would rely on their misrepresentations and omissions. Through their scheme, CVS Caremark, OptumRx, and Express Scripts leveraged formulary control for ever-increasing Manufacturer Payments while the Manufacturer Defendants maintained or increased their profit margins or sales volume as preferred formulary members. Defendants intended to profit at the expense of payors like Plaintiff.

754. Plaintiff reasonably relied on these Defendants' deception, and these Defendants intended that they would so rely. Plaintiff had no way of discerning the Defendants' deceit, as they possessed exclusive knowledge regarding the nature of diabetes drug pricing; the Defendants intentionally concealed the foregoing from Plaintiff and the public; and made incomplete or false representations about the pricing of the at-issue drugs and their role in that pricing, while purposefully withholding material facts from Plaintiff that contradicted these representations.

755. Plaintiff relied on these Defendants' false list prices. Because of the Insulin Pricing Scheme, list prices have skyrocketed and the spread between list price and net price has ballooned in turn. Plaintiff is injured by this list and net price divergence. Through the scheme, these Defendants have forced payors, including Plaintiff, to pay not just for the drugs, but also for undisclosed kickbacks that are paid to PBMs.

756. These Defendants took deliberate steps to ensure that their employees and co-conspirators did not disclose the details of the Insulin Pricing Scheme to Plaintiff.

757. These Defendants owed Plaintiff a duty to disclose, truthfully, all facts concerning the true cost of the at-issue medications and the inflated and fraudulent nature of their pricing; the existence, amount, flow, and purpose of rebates and discounts negotiated for those products; and the role that Defendants played in increasing the price of the at-issue drugs.

758. These Defendants possessed superior knowledge of essential facts about the at-issue drugs and their prices. That information was peculiarly and exclusively in their control and not available to payors, including Plaintiff. In light of their misleading or incomplete representations, these Defendants also had an obligation to disclose facts related to the Insulin Pricing Scheme.

759. These Defendants hatched their deceptive schemes and knew that Plaintiff did not know (and could not reasonably discover) that they sought to artificially inflate the price of the insulin medications. These Defendants not only concealed all the facts concerning the true cost of the at-issue medications but went further to make affirmative misrepresentations in marketing materials and other communications that these Defendants worked to lower the ultimate cost of prescription medications. These Defendants engaged in this fraudulent concealment at the expense of Plaintiff.

760. Plaintiff was not aware of the concealed and misrepresented material facts referenced above, and they would not have acted as they did, had they known the truth.

761. As a direct and proximate result of these Defendants' fraudulent scheme, Plaintiff sustained damages, including but not limited to paying excessive and inflated prices for the at-issue medications.

762. These Defendants valued their profits over the trust, health, and safety of Plaintiff and diabetics across the country. These Defendants repeatedly misrepresented the price of the at-issue drugs.

763. These Defendants' actions, misrepresentations, and omissions demonstrate callous disregard for not only the rule of law but also public health.

Indeed, as a direct result of these Defendants' actions, access to live-saving diabetes medications has been limited, denied, or forgone.

764. CVS Caremark, OptumRx, Express Scripts, and the Manufacturer Defendants are liable to Plaintiff for damages in an amount to be proven at trial. Moreover, because these Defendants acted wantonly, maliciously, oppressively, recklessly, deliberately, and with intent to defraud Plaintiff and for the purpose of enriching themselves to the public's detriment, Defendants' conduct warrants punitive damages in an amount to be determined at trial.

COUNT FIVE

Civil Conspiracy
(Against All Defendants)

765. Plaintiff re-alleges and incorporates by reference all preceding and succeeding factual allegations.

766. Plaintiff brings this claim against all Defendants.

767. The Defendants' conduct—namely, the conduct described throughout this Complaint as comprising and implementing the Insulin Pricing Scheme—constituted a combination of two or more persons created to accomplish an unlawful purpose or a lawful purpose by unlawful means, which resulted in damage to Plaintiff.

768. Each and every Defendant knowingly participated in the creation and implementation of the Insulin Pricing Scheme.

769. Each and every Defendant planned, assisted, and encouraged the Insulin Pricing Scheme.

770. Defendants aided and abetted one another to violate federal laws and the Virginia Consumer Protection Act, as alleged herein.

771. Each Defendant agreed to carry out and carried out acts in furtherance of the Insulin Pricing Scheme that artificially inflated the price of diabetes medications to Plaintiff's detriment.

772. Each PBM Defendant made a conscious commitment to participate in the Insulin Pricing Scheme.

773. Manufacturer Defendants agreed with each other and PBM Defendants to intentionally raise their diabetes medication prices, a significant portion of which would then be paid back to the PBMs.

774. In exchange for Manufacturer Defendants inflating their prices and making large secret payments, PBM Defendants agreed to and did grant preferred formulary status to Manufacturer Defendants' diabetes medications.

775. Each Defendant shares a common purpose of perpetuating the Insulin Pricing Scheme and neither the PBM Defendants nor Manufacturer Defendants

alone could have accomplished the Insulin Pricing Scheme without their co-conspirators.

776. PBM Defendants need Manufacturer Defendants to inflate the list price of their diabetes medications and to make secret payments back to PBM Defendants in order for PBM Defendants to profit from the Insulin Pricing Scheme.

777. Manufacturer Defendants need PBM Defendants to grant certain diabetes medications preferred formulary placement in order to maintain access to payors and patients, whose purchase of the at-issue drugs generated unearned and unwarranted revenue for all Defendants.

778. As discussed throughout this Complaint, the Insulin Pricing Scheme resulted from explicit agreements, direct coordination, constant communication, and exchange of information between the PBMs and the Manufacturers.

779. As alleged extensively throughout this complaint, Defendants affirmatively misrepresented and/or concealed and suppressed material facts concerning: (a) the actual cost and/or price of the diabetes medications realized by Defendants; (b) the inflated and/or fraudulent nature of the reported prices set and/or charged by Defendants for the diabetes medications described herein; (c) the existence, amount, and/or purposes of Manufacturer Payments, discounts and/or payments offered and/or negotiated by Defendants for those products; and (d) the role that Defendants played in the price paid for the diabetes medications described

herein, including but not limited to falsely representing that Defendants decrease the price of prescription drugs for payors like Plaintiff.

780. In fact, PBM Defendants base their entire business model around representing—directly and indirectly—to payors that they negotiate with Manufacturer Defendants, through rebates and formulary decisions, to lower the price that payors pay for diabetes medications.

781. Defendants' conspiracy also is demonstrated by the following indirect evidence that implies Defendants conspired to engage in fraudulent conduct:

a. Defendants refuse to disclose the details of their pricing structures, agreements, and sales figures in order maintain the secrecy of the Insulin Pricing Scheme;

b. Numerous government investigations, hearings, and inquiries have targeted the Insulin Pricing Scheme and the collusion between the Manufacturer and PBM Defendants, including:

- civil investigative demands to the Manufacturer Defendants from the States of California, Florida, Minnesota, and Washington relating to the pricing of their insulin products and their relationships with the PBM Defendants;
- letters from numerous senators and representatives in recent years to the Justice Department and the Federal Trade

Commission asking them to investigate potential collusion among Defendants;

- 2019 hearings before the House Oversight and Reform Committee on industry practices; and
- the Senate Finance Committee's recent two-year probe into the Insulin Pricing Scheme and the conspiracy between the Manufacturers and the PBMs, resulting in the Grassley-Wyden report, first published in 2021.

c. The astronomical rise in the price of insulin coincided with the PBM Defendants' increasing market power within the pharmaceutical pricing system.

782. Plaintiff was damaged and continues to be damaged by the conspiracy in that it overpaid for the at-issue diabetes medications as result of Defendants' unlawful actions.

783. By virtue of their conspiracy, Defendants are jointly and vicariously liable for the violations described herein.

COUNT SIX

Unjust Enrichment
(Against All Defendants)

784. Plaintiff re-alleges and incorporates by reference all preceding and succeeding factual allegations.

785. Plaintiff brings this claim against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, OptumRx, and CVS Caremark. All are referred to collectively throughout Count Five as "Defendants."

786. This claim is alleged in the alternative to Plaintiff's claims for legal relief.

787. It is a fundamental principle of fairness and justice that a person should not be unjustly enriched at the expense of another.

788. A person should not be unjustly enriched at the expense of another even if that person's conduct is not tortious.

789. Defendants jointly and severally deceived Plaintiff and have received a financial windfall from the Insulin Pricing Scheme at Plaintiff's expense.

790. Plaintiff conferred a benefit on Defendants by directly purchasing the at-issue insulins from Defendants at artificially and illegally inflated prices as established by the Insulin Pricing Scheme.

791. Plaintiff unknowingly conferred this benefit upon Defendants to Plaintiff's financial detriment.

792. Defendants, jointly and severally, wrongfully secured and retained a benefit in the form of amounts paid for diabetes medications, unearned fees and other payments collected based on the market forces and prices generated by the Insulin

Pricing Scheme, and revenues that would not have been realized but for the Insulin Pricing Scheme.

793. Defendants, jointly and severally, wrongfully secured and retained a benefit in the form of revenues and profits to which they were not entitled, which did not represent the fair market value of the goods or services they offered, and which were obtained at Plaintiff's expense.

794. Defendants, jointly and severally, wrongfully secured and retained a benefit in the form of drug monies paid at prices that would not have existed but for Defendants' misconduct.

795. Defendants were aware of the benefit, voluntarily accepted it, and retained and appreciated the benefit, to which they were not entitled, all at Plaintiff's expense.

796. Because Defendants knew of the benefit unjustly conferred on them by Plaintiff—the purchase of insulin medications at artificially inflated prices—Defendants should have reasonably expected to repay that benefit to Plaintiff.

797. Instead, Defendants retained the revenue resulting from the sale of insulin at artificially inflated prices. Any Defendant's retention of any portion of any benefit obtained by way of the Insulin Pricing Scheme is unjust and inequitable regardless of the Insulin Pricing Scheme's legality.

798. Each and every Defendant's retention of any portion of the benefit violates the fundamental principles of justice, equity, and good conscience. Even absent Plaintiff's ability to prove the elements of any other claim, it would be unfair, unjust, and inequitable for any Defendant to retain any portion of the benefit.

799. Even absent legal wrongdoing by any or all Defendants, Plaintiff has a better claim to the benefit than any and all Defendants.

800. The benefit retained is in an amount not less than the difference between the reasonable or fair market value of the at-issue drugs for which Plaintiff paid and the actual value of the at-issue drugs these Defendants delivered and, as to the PBM Defendants Express Scripts, OptumRx, and CVS Caremark, the reasonable or fair market value of the services for which Plaintiff paid and the actual value of services rendered with respect to the at-issue drugs.

801. Defendants should not be permitted to retain the benefit conferred upon them by Plaintiff and restitution is appropriate to prevent the unjust enrichment.

802. Accordingly, Plaintiff seeks disgorgement of the benefit and seeks restitution, rescission, or such other relief as will restore to Plaintiff that to which it is entitled.

VII. MOTION FOR INJUNCTION

803. Plaintiff re-alleges and incorporates by reference all preceding and succeeding factual allegations.

804. By Defendants' violations of the Virginia Consumer Protection Act, RICO, and the common law, Plaintiff has suffered, and will continue to suffer, immediate and irreparable injury, loss, and damage, as discussed herein.

805. The ongoing and threatened injury to Plaintiff and its Plan Participants, as well as to other consumers, outweighs the harm that an injunction might cause Defendants.

806. As a direct and proximate result of Defendants' conduct in committing the above and foregoing acts, Plaintiff moves this Honorable Court for injunctive relief against Defendants pursuant the Virginia Consumer Protection Act and 18 U.S.C. § 1964(a), thereby enjoining Defendants from committing future violations of the VCPA and RICO.

807. Granting an injunction is consistent with the public interest because it will protect the health and economic interests of Plaintiff, as well as the integrity of the Virginia marketplace.

VIII. PRAYER FOR RELIEF

808. WHEREFORE, Plaintiff prays for entry of judgment against the Defendants for all the relief requested herein and to which the Plaintiff may otherwise be entitled, specifically, but without limitation, as follows:

a. That the Court determine that Defendants have violated the Virginia Consumer Protection Act, have violated RICO, have been unjustly

enriched, have committed common law fraud, and have engaged in a civil conspiracy;

b. Judgment in favor of Plaintiff and against the Defendants for damages in excess of the minimum jurisdictional requirements of this Honorable Court, in a specific amount to be proven at trial;

c. Injunctive relief in accordance with the VCPA and 18 U.S.C. § 1964(a), to the effect that Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy or combination alleged herein in violation of Virginia law and RICO, or from entering into any other contract, conspiracy, or combination having a similar purpose or effect; from adopting or following any practice, plan, program or device having a similar purpose or effect; and from continuing their practice of publishing false list prices;

d. That Plaintiff:

   i. be awarded treble damages pursuant to 18 U.S.C. § 1964(c);

   ii. be awarded restitution, damages, disgorgement, penalties and/or all other legal and equitable monetary remedies available under the

state laws set forth in this Complaint, and the general equitable powers of this Court in an amount according to proof;

iii. be awarded punitive damages because Defendants knowingly, willfully, wantonly and intentionally harmed the health, wellbeing, and financial interests of Plaintiff and its Beneficiaries;

iv. be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the initial Complaint in this action;

v. recover its costs of this action, including its reasonable attorneys' fees; and

vi. be awarded such other further relief as the case may require and the Court may deem just and proper under the circumstances.

IX. JURY DEMAND

Plaintiff demands trial by jury on all issues so triable.

Date: August 1, 2024

RESPECTFULLY SUBMITTED,

CITY OF ALEXANDRIA, VIRGINIA

s/ Mark Pifko

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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2024, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to all counsel of record.

s/ Mark Pifko
Mark Pifko